UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

THERESA PITMAN, Individually and on Behalf of All Others Similarly Situated,

CLASS ACTION

Plaintiff,

SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Civil Action No. 1:21-cv-00918-KAM-VMS

VS.

IMMUNOVANT, INC. f/k/a HEALTH
SCIENCES ACQUISITIONS
CORPORATION, RODERICK WONG,
PETER SALZMANN, FRANK M. TORTI,
ANDREW FROMKIN, DOUGLAS HUGHES,
GEORGE MIGAUSKY, ATUL PANDE,
ERIC VENKER, SVB LEERINK LLC,
LIFESCI CAPITAL LLC, CHARDAN
CAPITAL MARKETS LLC, GUGGENHEIM
SECURITIES, LLC, ROBERT W. BAIRD &
CO. INCORPORATED, and ROIVANT
SCIENCES LTD.,

Defendants.

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

	rage
NATURE OF THE ACTION	1
JURISDICTION AND VENUE	4
BASIS OF ALLEGATIONS	4
THE PARTIES	6
Lead Plaintiff	6
Defendants	6
CLASS ACTION ALLEGATIONS	10
SUBSTANTIVE ALLEGATIONS	13
The Company and Its Business	13
Background of HSAC and the Merger with Legacy Immunovant	15
Roivant Controlled Immunovant and Was Intimately Involved with the Development of IMVT-1401	17
The FDA Drug Testing and Approval Process	22
Immunovant Was Required to Assess the Safety of IMVT-1401 Before and During Clinical Trials	24
A Potential Risk of IMVT-1401 Was Elevated LDL and Cholesterol Levels and Cardiovascular Disease	28
Immunovant's Pre-Clinical Animal Studies Clearly Showed that IMVT-1401 Substantially Raised the Cholesterol Levels of Animals	30
Numerous Studies Reported that FcRn Inhibition and Reduced Serum Albumin Levels, Such as Caused by IMVT-1401, Impact Cholesterol and Increase Risk for Cardiovascular Disease	32
Thyroid Hormone Levels, Such as the Levels Impacted by Grave's Ophthalmopathy and Myasthenia Gravis, Are Connected to Cholesterol Levels	36
Even Though Increased Cholesterol Was a Potential Risk of IMVT-1401, Immunovant Failed to Monitor or Assess Cholesterol in Early Clinical Trials	37

	Page
A Reasonable Investor Would Have Expected (i) IMVT-1401 Clinical Trials to Monitor Key Potential Risks, such as Cholesterol, and (ii) that Statements about IMVT-1401 Clinical Trials Were Based on an Assessment of Key Potential Risks, such as Cholesterol	
THE SEPTEMBER 2020 OFFERING DOCUMENTS CONTAINED INACCURATE STATEMENTS OF MATERIAL FACT AND OMITTED MATERIAL INFORMATION REQUIRED TO BE DISCLOSED THEREIN	41
Statements Concerning IMVT-1401's Clinical Trials	43
Statements Concerning the Potential Negative Impact of Albumin Reductions	50
Statements Concerning IMVT's Nonclinical Animal Studies	51
Statements Concerning Compliance with Good Clinical Practices	52
The September 2020 Offering Documents Omitted Known Trends, Events and Uncertainties that Were Impacting, and Would Impact, the Company's Financial Results	53
The September 2020 Offering Documents Omitted to Include Significant Factors that Made the Offering Risky	55
Any Purported Risk Warnings in the September 2020 Offering Documents Were Inadequate	56
Immunovant's Updated Cautionary Language After the Class Period Illustrates the Inadequacies of Its Class Period Cautionary Language	58
The Company's Stock Declines	60
Immunovant's Emphasis on a New Drug Called IMVT-1402 Illustrates the Importance of the Elevations in Cholesterol Caused by IMVT-1401	65
COUNT I	69
Violations of Section 11 of the Securities Act Against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants	69
COUNT II	71
Violations of Section 12(a)(2) of the Securities Act Against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants	71

	Page
COUNT III	73
Violations of Section 15 of the Securities Act Against the Securities Act Individual Defendants and Roivant	73
ADDITIONAL ALLEGATIONS IN SUPPORT OF CLAIMS UNDER THE EXCHANGE ACT	74
The Fraudulent Scheme: Immunovant Delayed the Monitoring and Assessment of Cholesterol Levels and the Disclosure of the Potential Risk of Cholesterol Elevations to Provide Time to Raise Hundreds of Millions of Dollars in Stock Offerings and to Obtain 20 Million Earnout Shares	74
MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD	75
Misstatements and Omissions Regarding Immunovant's Compliance with Good Clinical Practices	85
Defendants Continued Making Materially False and Misleading Statements and Omitted Material Information	86
Additional Misstatements and Omissions Regarding IMVT-1401 Clinical Trials	87
Additional Misstatements and Omissions Regarding the Impact of Albumin Reductions and the Existence of Studies Indicating Albumin Reductions Elevate Cholesterol	102
Additional Misstatements and Omissions Regarding IMVT's Animal Studies	105
Immunovant's Class Period SEC Filings Omitted Known Trends, Events and Uncertainties that Were Impacting, and Would Impact, the Company's Financial Results	106
Immunovant's Class Period SEC Filings Omitted to Include Significant Risk Factors Required to Be Disclosed Therein	106
ADDITIONAL SCIENTER ALLEGATIONS	107
LOSS CAUSATION/ECONOMIC LOSS	116
APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE	117

	Page
APPLICABILITY OF PRESUMPTION OF RELIANCE: AFFILIATED UTE DOCTRINE	118
NO SAFE HARBOR	119
COUNT IV	119
Violations of Section 10(b) of the Exchange Act and Rules 10b-5(a), (b), and (c) Promulgated Thereunder Against Immunovant, Roivant and the Exchange Act Individual Defendants	119
COUNT V	123
Violations of Section 20(a) of the Exchange Act Against the Exchange Act Individual Defendants and Roivant	123
PRAYER FOR RELIEF	125
DEMAND FOR TRIAL BY JURY	125

Lead Plaintiff SEPTA Pension Plan Master Trust ("Plaintiff" or "SEPTA"), by its undersigned attorneys, on behalf of itself and the class it seeks to represent, for its Second Amended Complaint for Violations of the Federal Securities Laws (the "Complaint"), alleges the following upon knowledge as to its own acts, and upon the investigation conducted by Plaintiff's counsel as detailed below.

NATURE OF THE ACTION

- 1. This is a federal securities class action on behalf of all purchasers, other than Defendants (defined below), of the securities of Immunovant, Inc. f/k/a Health Sciences Acquisitions Corporation ("HSAC," "Immunovant," or the "Company"), in or traceable to the Company's follow-on public offering on or about September 2, 2020 (the "September 2020 Offering"), as well as purchasers of the Company's securities between October 2, 2019 and February 1, 2021, inclusive (the "Class Period"), under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 ("Securities Act") and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).
- 2. Immunovant is a clinical-stage biopharmaceutical company developing a drug to treat several types of autoimmune diseases. This drug, referred to as "IMVT-1401" or "Batoclimab," was Immunovant's only product during the Class Period. Since IMVT-1401 was in the clinical trial stage during the Class Period, Immunovant did not generate any sales or profits. Immunovant's operations focused exclusively on overseeing and managing the clinical trial process for IMVT-1401 with the goal of selling the drug after approval by the U.S. Food and Drug Administration ("FDA").
- 3. Before the start of the Class Period, Immunovant was a private company ("Legacy Immunovant") and a division of Defendant Roivant (defined below). Defendant Roderick Wong ("Wong") invested in Legacy Immunovant and owned approximately 3% of its shares. Immunovant

became a public company when a special purpose acquisition company ("SPAC"), sponsored and run by Defendant Wong, acquired it in a deal valued at more than \$400 million. Roivant continued to control Immunovant and be its majority shareholder after the merger.

- 4. During the Class Period, Defendants praised the widespread benefits of IMVT-1401 and the results of its early clinical trials. Unbeknownst to investors, however, there was a potential risk that IMVT-1401 could elevate LDL and cholesterol levels and increase the risk of cardiovascular disease for patients taking the drug. Instead of informing investors about this important and substantial potential risk, Defendants made rosy statements about IMVT-1401, highlighted the positive results from IMVT-1401's early clinical trials, and described IMVT-1401 as a "best-in-class" drug that was "safe" and "well-tolerated" with "no serious adverse events" and "no withdrawals due to adverse events."
- 5. Throughout the Class Period, Defendants misrepresented and failed to disclose to investors, among other things, that: (i) IMVT-1401 was less safe than the Company had led investors to believe; (ii) there was a potential risk IMVT-1401 would substantially increase LDL and total cholesterol levels; (iii) Immunovant failed to monitor and assess the important potential risk of elevated LDL or cholesterol levels in any of its Phase 1 or 2a clinical trials; (iv) Immunovant failed to follow FDA regulations and Good Clinical Practices in connection with IMVT-1401; and (vi) Immunovant's business, operations and financial condition were not as represented.
- 6. As detailed below, numerous facts indicated elevated LDL and cholesterol levels were a potential risk of IMVT-1401, including: (i) IMVT-1401's preclinical animal studies revealed substantial elevations in cholesterol of animals which received IMVT-1401; (ii) IMVT-1401 reduces a protein named serum albumin and numerous scientific studies and articles indicated albumin reductions elevate cholesterol; (iii) IMVT-1401 targets thyroid conditions and numerous scientific

studies connect thyroid issues to cholesterol; and (iv) companies developing similar drugs monitored cholesterol levels.

- 7. Defendants' misrepresentations and omissions about Immunovant and IMVT-1401 caused an artificial inflation in the price of Immunovant securities and pushed Immunovant common stock above predetermined price thresholds, enabling Defendants Roivant and Wong (and others) to be awarded 20 million shares of Company stock valued at more than \$600 million. The price of Immunovant stock reached a high of \$50.67 during the Class Period. The rise in the price of Immunovant common stock enabled Defendant Immunovant and others to sell hundreds of millions of dollars of Company stock to investors through several follow-on stock offerings, including an offering on or about September 2, 2020. As alleged below, the offering documents for the September 2, 2020 offering contained untrue statements of material fact and omitted material information about IMVT-1401 and give rise to Plaintiff's Securities Act claims.¹
- 8. On February 2, 2021, the Company announced it halted a Phase 2b clinical trial of IMVT-1401 referred to as the ASCEND GO-2 Phase 2b trial and stated it had "become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients." An analyst report by UBS on February 5, 2021 described the cholesterol data as "a very real and meaningful increase in LDL levels (40-65%)."
- 9. Following the Company's February 2, 2021 announcements, the price of Immunovant stock collapsed from a closing price of \$43.30 per share on February 1, 2021 to a closing price of \$25.08 per share on February 2, 2021, a one day decline of \$18.22 per share, or 42.08%, on extremely heavy trading volume of 11.76 million shares. On June 1, 2021, Immunovant announced additional details about the elevated levels of cholesterol, including there was a link between IMVT-

¹ The August 31, 2020 Registration Statement and September 1, 2020 Prospectus are collectively referred to herein as the "September 2020 Offering Documents."

1401 and cholesterol. Following the Company's June 1, 2021 announcements, the price of Immunovant stock fell from a closing price of \$15.16 per share on Friday, May 28, 2021, to a closing price of \$9.40 per share on June 1, 2021, a one day decline of \$5.76 per share, or 38%, on extremely heavy trading volume of 16.91 million shares.

JURISDICTION AND VENUE

- 10. The claims asserted herein arise under and pursuant to Sections 11, 12(a)(2) and 15 of the Securities Act [15 U.S.C. §§77k, 77l(a)(2) and 77o], Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder [17 C.F.R. §240.10b-5].
- 11. This Court has jurisdiction over this action pursuant to Section 22 of the Securities Act [15 U.S.C. §77v], Section 27 of the Exchange Act [15 U.S.C. §78aa], and 28 U.S.C. §§1331 and 1337.
- 12. Venue is properly laid in this District pursuant to Section 22 of the Securities Act, Section 27 of the Exchange Act, and 28 U.S.C. §1391(b) and (c). The acts and conduct complained of herein occurred in substantial part in this District, and the September 2020 Offering was marketed in this District.
- 13. In connection with the acts and conduct alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephonic communications and the facilities of the national securities markets.

BASIS OF ALLEGATIONS

14. The allegations herein are based upon the investigation conducted by and under the supervision of Plaintiff's counsel, which included interviewing former Immunovant employees and reviewing and analyzing information from numerous public and proprietary sources (such as LexisNexis, Dow Jones and Bloomberg, Inc.), including, *inter alia*, SEC filings, other regulatory

filings and reports, publicly available annual reports, press releases, published interviews, news articles and other media reports, reports of securities analysts, and public data related to Immunovant's testing and development of IMVT-1401, in order to obtain the information necessary to plead Plaintiff's claims with particularity where necessary.

- 15. Additionally, Plaintiff's counsel, with the assistance of consultants with extensive clinical, drug development, pharmacovigilance, and protocol development experience, reviewed and analyzed publicly available information about IMVT-1401 and publicly available information about the underlying conditions identified by Immunovant as indications for IMVT-1401. Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.
- 16. Finally, as part of their investigation into the facts underlying this action, Plaintiff's counsel interviewed a former employee ("FE") of Immunovant who worked as a senior employee in Immunovant's Non-Clinical Development group from the end of 2019 until after the Class Period and was hired by Immunovant after two-decades of experience in preclinical drug development. FE has a pathology background with a specialization in cardiovascular diseases and is a board-certified toxicologist. FE has direct first-hand knowledge of Immunovant's pre-clinical and clinical testing of IMVT-1401 and the facts alleged herein. FE had oversight regarding the design, monitoring, data analysis, and reporting of non-clinical study profiles and directed nonclinical strategies necessary to progress drug candidates from preclinical development to clinical trials. FE paid attention to whether a drug candidate had negative impacts. FE has experience with regulatory submissions, general toxicology, and safety pharmacology.
 - 17. FE personally read the IMVT-1401 animal studies in connection with FE's

² Counsel for Plaintiff met with FE via zoom and telephone.

employment at Immunovant and was employed at Immunovant when the ASCEND GO-2 Phase 2b trial was halted. FE has substantial experience with preclinical studies and in reviewing written preclinical study reports. FE provided first-hand knowledge about IMVT-1401's animal testing and the halting of Immunovant's Phase 2b trial, as announced on or about February 2, 2021.

THE PARTIES

Lead Plaintiff

18. Lead Plaintiff SEPTA acquired the common stock of Immunovant as set forth in the certification previously filed with the Court and incorporated by reference herein during the Class Period and pursuant and/or traceable to the September 2020 Offering, and was damaged thereby.

Defendants

- 19. Defendant Immunovant is a Delaware corporation with principal executive offices located at 320 West 37th Street, New York, New York 10018. The Company's common stock trades in an efficient market on the NASDAQ under the ticker symbol "IMVT." Prior to the Merger, the Company (*i.e.*, HSAC) was a Delaware corporation with principal executive offices located at 412 West 15th Street, Floor 9, New York, New York 10011, and its securities traded on the NASDAQ under the ticker symbols "HSACU," "HSAC," and "HSACW."
- 20. Defendant Roivant Sciences Ltd. ("Roivant") is an integrated pharma-tech business which founds and funds biopharmaceutical and health technology companies. Defendant Roivant was a controlling shareholder of the Company at all relevant times herein. Legacy Immunovant began as a division of Roivant and Roivant owned more than 57% of Immunovant's outstanding common stock just prior to the September 2020 Offering and continued to own a controlling interest after that offering.
 - 21. Defendant Peter Salzmann, M.D. ("Salzmann") has served as Immunovant's Principal

Executive Officer and Chief Executive Officer ("CEO") since June 2019 and as a member of the Company's board of directors since October 2019. Salzmann was Head of U.S. Immunology at Eli Lilly from May 2013 through October 2018. Defendant Salzmann signed the September 2020 Offering Registration Statement.

- 22. Defendant Roderick Wong ("Wong") served as Health Sciences Acquisitions Corporation's ("HSAC's") President and CEO beginning in January 2019, and as Chairman of the board of directors since HSAC's inception in December 2018, both prior to the merger with Legacy Immunovant. Wong resigned as CEO of HSAC following the closing of the merger in December 2019. Defendant Wong served as Managing partner and Chief Investment Officer at RTW Investments, L.P. ("RTW"), a healthcare-focused investment firm, since 2010. Defendant Wong is also involved in other RTW Entities including RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd., and RTW Venture Fund Limited, where he has dispositive and voting powers over shares owned by these entities.
- 23. The Defendants referenced above in ¶21-22 are referred to herein as the "Exchange Act Individual Defendants."
- 24. Defendant Frank M. Torti, M.D. ("Torti") served as Chairperson of the Board of Directors of Immunovant during the Class Period. Beginning in June 2019, Defendant Torti served as Chairperson of the Board of Directors of Legacy Immunovant. Defendant Torti also served as the Vant Chair of Roivant Sciences, Inc., beginning in January 2020. From August 2018 through December 2019, Defendant Torti served as Vant Investment Chair of Roivant Sciences, Inc. Defendant Torti signed or authorized the signing of the September 2020 Offering Registration Statement.
 - 25. Defendant Andrew Fromkin ("Fromkin") served as a director of Immunovant during

the Class Period. Beginning in October 2019, Defendant Fromkin was a director of Legacy Immunovant. Beginning in January 2021, Defendant Fromkin served as Vant Portfolio Operating Partner at Roivant Sciences. Defendant Fromkin signed or authorized the signing of the September 2020 Offering Registration Statement.

- 26. Defendant Douglas Hughes ("Hughes") served as a director of Immunovant during the Class Period. Beginning in October 2019, Defendant Hughes was a director of Legacy Immunovant. Defendant Hughes signed or authorized the signing of the September 2020 Offering Registration Statement.
- 27. Defendant George Migausky ("Migausky") served as a director of Immunovant during the Class Period. Defendant Migausky also served as a director of HSAC from March 2019 to December 2019. Defendant Migausky signed or authorized the signing of the September 2020 Offering Registration Statement.
- 28. Defendant Atul Pande, M.D. ("Pande") served as a director of Immunovant during the Class Period. Beginning in October 2019, Defendant Pande was a director of Legacy Immunovant. Defendant Pande signed or authorized the signing of the September 2020 Offering Registration Statement.
- 29. Defendant Eric Venker, M.D., Pharm. D., ("Venker") served as a director of Immunovant during the Class Period. Beginning in November 2018, Defendant Venker served as Chief Operating Officer at Roivant Sciences, Inc. Defendant Venker signed or authorized the signing of the September 2020 Offering Registration Statement.
- 30. The Defendants referenced above in ¶21, 24-29 are referred to herein as the "Securities Act Individual Defendants."
 - 31. Defendant SVB Leerink LLC ("SVB Leerink") operates as an investment bank

specializing in healthcare and technology with its principal executive offices located in Boston, MA. SVB Leerink acted as a lead underwriter, joint bookrunning manager and as representative for the underwriters for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.

- 32. Defendant LifeSci Capital LLC ("LifeSci") is a boutique investment bank focusing on life sciences located in New York, NY. LifeSci acted as an underwriter for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.
- 33. Defendant Chardan Capital Markets LLC ("Chardan") is a global investment bank with its principal executive offices located in New York, NY. Chardan acted as an underwriter and joint bookrunning manager for the September 2020 Offering. Chardan helped to draft and disseminate the Prospectus for the September 2020 Offering.
- 34. Defendant Guggenheim Securities, LLC ("Guggenheim") operates as a global investment and advisory firm with its principal executive offices located in New York, NY. Guggenheim acted as a lead underwriter, joint bookrunning manager, and served as representative for the underwriters for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.
- 35. Defendant Robert W. Baird & Co. Incorporated ("Robert W. Baird") is a global investment bank and financial services company with its principal executive offices located in Milwaukee, WI. Robert W. Baird acted as an underwriter for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.
- 36. The Defendants referenced above in ¶31-35 are herein collectively referred to as the "Underwriter Defendants." The Underwriter Defendants failed to perform adequate due diligence in connection with their role as underwriters for the September 2020 Offering and were negligent in

failing to ensure that the Registration Statement and Prospectus for the September 2020 Offering were prepared properly and accurately. The Underwriter Defendants' failure to conduct an adequate due diligence investigation was a substantial factor leading to the harm complained of herein.

- 37. The Underwriters who drafted and disseminated the September 2020 Offering documents were paid approximately \$12 million in gross fees in connection therewith.
- 38. Defendants Immunovant, Roivant, the Securities Act Individual Defendants, the Exchange Act Individual Defendants, and the Underwriter Defendants are collectively referred to herein as "Defendants."

CLASS ACTION ALLEGATIONS

- 39. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Immunovant securities pursuant and/or traceable to the September 2020 Offering, as well as purchasers of the Company's securities during the Class Period (the "Class"), and were damaged thereby. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.
- 40. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Immunovant securities were actively traded on the NASDAQ and Immunovant sold more than 6 million shares of common stock in the September 2020 Offering. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Immunovant or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in

securities class actions.

- 41. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 42. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 43. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
 - whether the federal securities laws were violated by Defendants' acts as alleged herein;
 - whether the Prospectus and Registration Statement issued by Defendants to the investing public in connection with the September 2020 Offering negligently omitted and/or misrepresented material facts about Immunovant and its business;
 - whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Immunovant;
 - whether the Exchange Act Individual Defendants caused Immunovant to issue false and misleading financial statements during the Class Period;
 - whether the Exchange Act Individual Defendants and the Company acted knowingly or recklessly in issuing false and misleading financial statements;
 - whether the prices of Immunovant securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
 - whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 44. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the

damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

- 45. Plaintiff will rely, in part, upon the presumption of reliance established by the fraudon-the-market doctrine in that:
 - Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - the omissions and misrepresentations were material;
 - Immunovant securities are traded in an efficient market;
 - the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
 - the Company traded on the NASDAQ and was covered by multiple analysts;
 - the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
 - Plaintiff and members of the Class purchased, acquired and/or sold Immunovant securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 46. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
- 47. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

SUBSTANTIVE ALLEGATIONS

The Company and Its Business

- 48. Immunovant is a clinical-stage biopharmaceutical company that develops monoclonal antibodies for the treatment of autoimmune diseases. Autoimmune diseases are conditions where an immune response is inappropriately directed against the body's own healthy cells and tissues. Prior to and during the Class Period, Immunovant had a single drug in development. Immunovant's business focused on developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits the neonatal fragment crystallizable receptor ("FcRn"). Immunovant was developing IMVT-1401 as a fixed-dose, self-administered subcutaneous injection with an initial focus on the treatment of myasthenia gravis ("MG"), thyroid eye disease ("TED") (also known as Graves' ophthalmopathy ("GO")), and Warm Autoimmune Hemolytic Anemia ("WAIHA").
- 49. IMVT-1401 was originally developed by HanAll Biopharma, a South Korean company. On or about December 19, 2017, Roivant entered into a license agreement with HanAll Biopharma (the "License Agreement") under which HanAll granted Roivant "an exclusive license to develop, register, manufacture and commercialize products containing HL161BKN" outside of outside of Greater China (Hong Kong, Macau, and Taiwan). Roivant Sciences renamed the drug RVT-1401. During 2018, Roivant sought to develop RVT-1401 through a business unit formed as a private company named Immunovant Sciences Ltd. (referred to herein as "Legacy Immunovant"). Roivant launched Legacy Immunovant to develop treatment candidates for autoimmune disorders and specifically to develop RVT-1401, which it renamed IMVT-1401. While Roivant and Immunovant were developing IMVT-1401, Harbour BioMed, a Chinese biotech company, was developing its version of IMVT-1401, named HBM9161, in Greater China pursuant to a license it acquired from HanAll Biopharma.

- 50. The License Agreement provided Roivant with "an exclusive license to develop, register, manufacture and commercialize" the compound and "develop" included clinical, non-clinical development, and preclinical, clinical and other regulatory trials. Further pursuant to the License Agreement, Roivant and HanAll created a Joint Development Committee ("JDC") for the exchange of information related to the development of the compound. The License Agreement provided that "HanAll shall conduct a research program...(ii) including certain process optimization, scale-up and non-clinical studies for HL161BKN" and "shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of HanAll[.]" The License Agreement further provided that "[o]n or before the Initiation of the first Phase 1 Clinical Trial in the Territory...Roivant shall assume responsibility for and thereafter maintain the global safety database for Compounds and Licensed Products."
- 51. Roivant was intimately involved with and knowledgeable about IMVT-1401 and its development because it acquired its license and developed IMVT-1401 through its Legacy Immunovant subsidiary.
- 52. Defendant Wong was also knowledgeable about IMVT-1401 since before the Class Period in connection with RTW's investment in Legacy Immunovant. Defendant Wong created his investment firm RTW in 2009 and focused on investing in the healthcare industry across the life sciences space and supported companies through the FDA approval process and the commercialization of drugs. On or about December 28, 2018, Defendant Wong, through RTW, purchased more than 2.6 million (or approximately 3% of) Legacy Immunovant shares.

Background of HSAC and the Merger with Legacy Immunovant

- 53. HSAC was a blank check company formed for the purpose of effecting a merger, asset acquisition, or similar business combination. A SPAC is a blank check company formed solely to raise capital through an initial public offering ("IPO") and then use the money to acquire businesses thereafter. Money raised during the SPAC's IPO is commonly placed in a trust account until a certain amount of time passes or the SPAC enters a business combination. The SPAC founders have a financial stake in finding a company to acquire because they invest capital and receive shares in the SPAC and if an acquisition is not made within a specified time period (*i.e.*, within 18 to 24 months) the SPAC is typically dissolved, and the capital raised from the IPO must be returned to investors.
- 54. HSAC disclosed that it sought to pursue prospective targets focused on healthcare innovation. Health Sciences Holdings, LLC ("HSH") was HSAC's sponsor, which was operated by Defendant Wong, and an affiliate of RTW, which Defendant Wong also controlled.
- 55. HSAC raised approximately \$115 million from investors in its IPO on or about May 9, 2019. The proceeds from the IPO were deposited into a trust account for the benefit of the public shareholders. In connection with the IPO, HSAC's sponsor (HSH) acquired 10 million convertible warrants for \$5 million. HSAC had 24 months from the closing of its IPO in May 2019 to consummate a transaction. If HSAC failed to do so, it would have had to redeem 100% of its outstanding public shares, liquidate and dissolve. Upon dissolution, any public warrants would expire and all proceeds from the IPO would be returned to public shareholders.
- 56. On May 11, 2019, *merely two days after HSAC's IPO*, Defendant Wong, who was CEO of HSAC at the time, contacted Mayukh Sukhatme, a Legacy Immunovant Director and the President of Roivant, to discuss the possibility of a transaction between HSAC and Legacy Immunovant. Thereafter, HSAC, with Wong as CEO, engaged in months of due diligence into

Legacy Immunovant and IMVT-1401. On July 31, 2019, after months of back-and-forth communications, the parties entered into a letter of intent for the transaction. Between August 1, 2019 and September 20, 2019, HSAC continued its review of due diligence materials. On September, 29, 2019, HSAC, Legacy Immunovant, and the sellers of Legacy Immunovant entered into the Share Exchange Agreement for HSAC's merger with Legacy Immunovant (the "Merger").

- 57. On October 2, 2019, HSAC and Legacy Immunovant announced in a press release (the "10/2/19 Press Release") they entered into a definitive share exchange agreement ("SEA") under which HSAC would acquire 100% of the issued and outstanding shares of Legacy Immunovant. As described in the 10/2/19 Press Release, upon the closing of the transactions, the Legacy Immunovant shareholders will sell to HSAC all the issued and outstanding Legacy Immunovant shares, and HSAC will issue (or reserve for issuance upon the exercise of options) approximately 43 million HSAC shares to the current Immunovant shareholders. The aggregate value of the consideration to be paid by HSAC in the business combination was more than \$421 million. Upon consummation of the Merger, Legacy Immunovant became a wholly owned subsidiary of HSAC, and HSAC changed its name to "Immunovant Inc."
- 58. Importantly, the SEA provided substantial financial benefits to Defendants Roivant and Wong if the price of Immunovant stock rose to predetermined price targets within specified time periods. Specifically, Defendants Roivant and Wong (through RTW), along with other Legacy Immunovant shareholders, were to receive 10 million shares of Immunovant stock at no cost "if the share price exceeds \$17.50 by March 31, 2023" and an additional 10 million shares "if the share price exceeds \$31.50 by March 31, 2025." As described in the 10/2/19 Press Release:

[Legacy] Immunovant shareholders may, subject to the terms of the SEA, receive up to an additional 20 million HSAC shares (the "Earnout Shares"): 10 million shares if the share price exceeds \$17.50 by March 31, 2023 and an additional 10 million shares if the share price exceeds \$31.50 by March 31, 2025... Furthermore, subject to terms of the SEA, 1.8 million of the sponsor's founder shares will be cancelled unless HSAC's common stock exceeds certain stock prices on substantially identical terms and conditions as the Earnout Shares.³

59. The Merger between HSAC and Legacy Immunovant was approved on December 16, 2019. At that time, the price of Immunovant stock was \$11.49 per share. As a result of the Merger, HSAC acquired all the issued and outstanding shares of Legacy Immunovant, and Legacy Immunovant became a wholly owned subsidiary of HSAC. Upon the closing of the Merger, HSAC changed its name to "Immunovant, Inc." Legacy Immunovant became a public company when it was acquired by HSAC through the Merger.

Roivant Controlled Immunovant and Was Intimately Involved with the Development of IMVT-1401

- 60. Roivant exercised control over Immunovant before and after the Merger and throughout the entire Class Period. As alleged herein: (i) Roivant formed and controlled Legacy Immunovant; (ii) Roivant acquired the licensing rights to develop IMVT-1401 outside China and initially developed it as RVT-1401; (iii) after the Merger, Roivant continued to be Immunovant's controlling stockholder such that Immunovant was a controlled company within the meaning of the listing rules of NASDAQ and therefore had access to non-public information about IMVT-1401; (iv) Immunovant and Roivant entered into multiple agreements, including the SEA, the License Agreement and the Information Sharing and Cooperation Agreement, which described the relationship and obligations of the two companies; and (v) Immunovant uses Roivant's platform, services, and financing to operate its business and develop IMVT-1401.
 - 61. The Merger was structured such that Roivant was to maintain control of Immunovant

Emphasis is added unless otherwise indicated herein.

after it became a public company. After the Merger, depending upon the exercise of redemption rights by certain shareholders, HSAC's public stockholders prior to the merger were expected to own between 13.8% to 21% of HSAC's non-redeemable shares, HSAC's directors, officers and affiliates were expected to own approximately 2% to 2.1% of HSAC's non-redeemable shares, and the shareholders of Legacy Immunovant were expected to own between 77% to 84.1% of HSAC's non-redeemable shares. Therefore, after the Merger Roivant continued to control Immunovant through its ownership of more than 50% of Immunovant's shares.

- 62. Roivant also owned all of the Company's Series A preferred stock entitling Roivant to appoint four Series A Preferred Directors, and due to Roivant's control over Immunovant, the Company was not required to have a majority of "independent directors." Since Immunovant had seven directors in total, Roivant was able to, and did, appoint a majority of Immunovant's directors. According to the September 2020 Offering Documents, "Roivant will be able to exercise control over all matters requiring stockholder approval, including the election of our directors and approval of significant corporate transactions."
- 63. The September 2020 Offering Documents discussed that Immunovant is controlled by Defendant Roivant, stating, in pertinent part, as follows:

Our Controlling Stockholder

Roivant is currently our majority stockholder, and we are a "controlled company" within the meaning of the listing rules of Nasdaq. We will remain a "controlled company" so long as 50% of the voting power for the election of directors is held by Roivant. As such, we are availing ourselves of certain controlled company exemptions under the Nasdaq listing rules. We are not required to have a majority of "independent directors" on our board of directors, as defined under the Nasdaq listing rules, or to have a compensation committee or a committee performing the director nominating function composed entirely of independent directors. Roivant will be able to exercise control over all matters requiring stockholder approval, including the election of our directors and approval of significant corporate transactions. In addition, Roivant, as the holder of Series A preferred stock, has the right to elect a certain number of Series A Preferred Directors in accordance with the provisions of our amended and restated charter.

- 64. Roivant controlled Immunovant through its board of directors and had influence over even more than the four it appointed. Roivant exercised influence over six of the board members, because, among other reasons: (i) they were originally on the board of directors of Legacy Immunovant, which was a Roivant business unit; (ii) they were employed by Roivant; and/or (iii) they were appointed to Immunovant's board of directors through Roivant's Series A Preferred shares. Defendant Wong, through RTW, exercised control over the seventh board member.
 - 65. The below chart reflects Roivant and Wong's influence over Immunovant's board:

I (D: /	D • //D/DXX/ + 0°1• /•
Immunovant Directors	Roivant /RTWAffiliations
Peter Salzmann CEO of Immunovant beginning in June 2019 Director of Immunovant beginning in December 2019, after the Merger	Director of Legacy Immunovant, a business unit of Roivant, beginning in October 2019
Frank M. Torti Chairperson of Immunovant's board beginning in December 2019, after the Merger	 Chairperson of the board of directors of Legacy Immunovant, a business unit of Roivant, beginning in June 2019 Elected Chairperson of Immunovant's board by Roivant, the holder of Immunovant's Series A Preferred Stock Vant Chair of Roivant Sciences, Inc., a Roivant subsidiary, beginning in January 2020. Vant Investment Chair of Roivant Sciences, Inc. from August 2018 to December 2019
Andrew Fromkin Director of Immunovant beginning in December 2019, after the Merger	 Director of Legacy Immunovant, a business unit of Roivant, beginning in October 2019 Vant Portfolio Operating Partner at Roivant Sciences beginning in January 2021
Douglas Hughes Director of Immunovant beginning in December 2019, after the Merger	 Director of Legacy Immunovant, a business unit of Roivant, beginning in October 2019 Elected director of Immunovant by Roivant, the holder of Immunovant's Series A preferred stock

George Migausky Director of Immunovant beginning in December 2019, after the Merger	Director of HSAC (through Wong/RTW) from March 2019 to December 2019
Atul Pande Director of Immunovant beginning in December 2019, after the Merger	 Director of Legacy Immunovant, a business unit of Roivant, beginning in October 2019 Elected director of Immunovant by Roivant, the holder of Immunovant's Series A preferred stock
Eric Venker Director of Immunovant beginning in February 2020	 Elected director of Immunovant by Roivant, the holder of Immunovant's Series A preferred stock Chief Operating Officer of Roivant Sciences, Inc., a Roivant subsidiary, beginning in November 2018

- 66. On or about December 28, 2018, Roivant and Legacy Immunovant entered into an Amended and Restated Information Sharing and Cooperation Agreement (the "Information Sharing and Cooperation Agreement amended the original agreement Roivant and Legacy Immunovant entered into on or about August 20, 2018. This agreement required Immunovant to share detailed information about its business and the development of IMVT-1401 with Roivant.
- 67. The Information Sharing and Cooperation Agreement entitled Roivant to "all material information with respect to [Immunovant] that Roivant reasonably requires in connection with the preparation by Roivant" of Roivant's SEC filings.
- 68. The Information Sharing and Cooperation Agreement provided Roivant with access to detailed information about IMVT-1401, including Immunovant's clinical and preclinical data, stating, in pertinent part, as follows:

The Company shall, and shall cause each of its Subsidiaries to, promptly, upon reasonable request, (A) make available to Roivant and its Representatives such information, documents and other materials...relating to the business of Company or any of its Subsidiaries and in its possession and control...as Roivant may from time to time reasonably request...; and (B) give Roivant and its Representatives (x) the right to examine and make copies of... any records of the Company or any of its Subsidiaries for any reasonable purpose, (y) reasonable access to the Company's and its Subsidiaries' offices, properties, and employees, and (z) the reasonable opportunity to discuss any matters with the Company's and its Subsidiaries' senior management...connection with any proper purpose. For the avoidance of doubt, proper purpose includes use by Roivant of any such information, data, documents or other materials for its own internal research purposes, including but not limited to, for purposes of analyzing, and/or deriving learnings from, clinical data provided by the Company to Roivant hereunder; provided that, except for such use rights, in no event does the provision of information hereunder grant Roivant any other rights or licenses under or to any of the Company's intellectual property, compounds, products or programs.

69. The September 2020 Offering Documents describe that Immunovant, even as a public company, was still dependent upon Roivant for important functions related to its business and the development of IMVT-1401, stating among other things:

We are a Member of the Roivant Family of Companies

We are a majority-owned subsidiary of Roivant and have benefited from our ability to leverage the Roivant model and the greater Roivant platform. The period of time between our formation and operational maturation was shortened based on the support from centralized Roivant functions available since its creation. This includes operational functions as well as access to Roivant's proprietary technology and digital innovation platforms. Consistent with its model, Roivant has also provided us with access to an embedded team of scientific experts, physicians and technologists to help optimize clinical development and commercial strategies. In the future, we may have the ability to benefit from Roivant's economies of scale and scope.

70. Roivant's support and involvement enabled Immunovant to test and develop IMVT-1401. The September 2020 Offering Documents state, in pertinent part: "[w]e have received, and will continue to receive, various services provided by our affiliates, Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG, each an indirect wholly owned subsidiary of Roivant. *These services include, but are not limited to, services related to development, administrative and*

financial activities...."

- 71. The interdependency between Roivant and Immunovant is reflected on Roivant's website, which lists Immunovant first among its subsidiaries.⁴
- 72. On January 8, 2021, Roivant issued a press release announcing an upcoming presentation at the Annual J.P. Morgan Healthcare Conference and discussed its recent milestones, including, "positive clinical data at...Immunovant[.]" On January 25, 2021, Roivant issued a press release providing an Annual Shareholder Update including an update on Immunovant's development of IMVT-1401 stating, it "ha[s] also made significant clinical progress at Immunovant (Nasdaq: IMVT)[.]" As a final example, Roivant's Form 10-Q filed with the SEC for the quarterly period ended June 30, 2021 tells investors to "carefully consider . . . other materials filed or *furnished by our majority-controlled subsidiary Immunovant, Inc. [] with the SEC.*"

The FDA Drug Testing and Approval Process

- 73. The process of drug development in the U.S. and elsewhere follows a standard sequence of experimental phases. The FDA regulates the sale and marketing of pharmaceutical products in the United States. The FDA reviews new drugs through New Drug Applications ("NDA"). Prior to approval, a drug typically goes through the pre-clinical and clinical trial stages. The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. The Clinical trials have three phases Phase I, II, III which must be successfully completed before submission of an NDA to the FDA.
- 74. Before the clinical trial stage, nonclinical studies precede human experimentation to develop a basic understanding of toxicity and potential adverse effects associated with the use of the drug, as well as to define potential dosages to be used in humans. A standard battery of tests are

⁴ See, https://roivant.com/companies (last visited February 24, 2023).

performed to determine organ toxicity, effects on the fetus, damage to DNA, and potential "off-target" effects.

- 75. The procedures for clinical trials and sponsor requirements are described in Title 21, Subchapter D of the Code of Federal Regulations. Part 312 describes the requirements for drugs studied under an Investigational New Drug ("IND") application. Prior to initiating any clinical trials involving human subjects, an IND application must be filed. Upon completion of the nonclinical (or preclinical) studies, the sponsor may also meet with the FDA for a pre-IND meeting. One of the purposes of this meeting is to discuss the rationale for safety monitoring based on the pharmacology and toxicology results known at that time. As an example, if elevations in cholesterol were noted in animal studies, it would be important for the sponsor to discuss with the FDA the proposed pharmacovigilance plan and its rationale. After submission of the first in human (FIH) study protocol, the FDA has 30 days to review the protocol before the study can be initiated in humans.
- 76. Phase 1 studies are designed to assess safety, typically in healthy volunteers. The studies will begin with single doses in ascending dose strength. Once a tolerable dose range is established, multiple doses are given to subjects to assess both safety and the pharmacokinetics of the drug in humans.⁶
- 77. Following Phase 1 studies, the sponsor will traditionally begin Phase 2 studies. These are studies in patient populations (such as myasthenia gravis or thyroid eye disease) and are primarily designed to determine an appropriate dose range for larger, Phase 3, or pivotal, studies. Safety should be carefully assessed during Phase 2 studies for signals of potential adverse reactions,

⁵ Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

⁶ Pharmacokinetics is the study of the time course of drug absorption, distribution, metabolism, and excretion.

particularly those that are severe and/or dose related.

78. Phase 3 studies are larger studies involving a broader population of patients with the disorder under study. These studies are considered pivotal for evidence of efficacy and safety by the FDA and, typically, two "adequate and well-controlled" studies are required by the FDA for review and approval.

79. Ultimately, the FDA has the final authority to determine the balance of (potential) benefits and risks in drugs under development and the FDA may impose a Partial or Complete Clinical Hold if a significant safety issue is identified. Therefore, it is incumbent upon the sponsor to conduct studies in compliance with CFR 312 and Good Clinical Practices, as defined in the International Conference on Harmonization (ICH) E6, in order to protect patients to the extent possible. An important part of that protection involves ongoing surveillance of adverse events⁷ and suspected adverse reactions.⁸

Immunovant Was Required to Assess the Safety of IMVT-1401 Before and During Clinical Trials

80. Immunovant, as the sponsor of IMVT-1401's clinical trials, was required to adhere to FDA rules, guidelines, and good clinical practices. Immunovant was expected to actively monitor and assess safety information about IMVT-1401 on an ongoing basis through a variety of methods to identify risks. Among other things, Immunovant was required to determine whether risks could be identified from adverse events in IMVT-1401's animal studies or those reported from other drugs

⁷ "Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related." U.S. Code of Federal Regulations, Title 21, Sec. 312.32(a).

⁸ "Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, 'reasonable possibility' means there is evidence to suggest a causal relationship between the drug and the adverse event." U.S. Code of Federal Regulations, Title 21, Sec. 312.32(a).

within IMVT-1401's pharmacological class.

- 81. The World Health Organization defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem." Pharmacovigilance is a process that requires regular and ongoing surveillance of safety data received during the conduct of a clinical trial. Commonly accepted PV practices were described by the Council for International Organizations of Medical Sciences (CIOMS) in CIOMS VI.
- 82. During the conduct of clinical trials, the sponsor is required to monitor and assess safety information on an ongoing basis, looking for the emergence of any new risks. Immunovant was required to assess safety data from all sources, including animal studies, clinical investigations, reports in scientific literature, unpublished scientific papers and numerous other places. And adverse events reported in other drugs within a pharmacological class or within the same drug in animal studies should have led to a heightened level of surveillance for anticipated risks.
- 83. Risks may be anticipated to occur in the patient population being studied (for example, stroke in a study of patients with atrial fibrillation) but imbalances between the treated group and the control group might suggest a greater risk associated with the drug. Furthermore, adverse events reported in other drugs within a pharmacological class or within the same drug in animal studies should lead to a heightened level of surveillance for anticipated risks, as described by the CIOMS VI Working Group:

The CIOMS VI Working Group considers the term "known risk" to refer to a risk that has been observed and is reasonably established for the investigational product itself; the term "anticipated risk" to refer to a risk that has not yet been observed or established for the product but is expected to occur based on knowledge of the class of drugs; and the term "potential risk" to refer to a risk that has not yet been observed in humans for the investigational product itself or for other drugs in the class but for which there is reason to suspect it might occur, based on animal toxicology studies or the known pharmacologic properties. In other contexts (e.g., ICH E2E), what we refer to as anticipated risks are usually placed in the potential risk category.

- 84. If new safety issues are identified, the sponsor is required to report these issues to regulatory authorities. When developing drugs under an IND, sponsors must adhere to the requirements for safety reporting as described in CFR 312.32. A Guidance for Industry was published by the FDA in 2005 describing IND Safety Reporting. This was updated in 2010 when the FDA published the Final Rule for IND Safety Reporting in the Federal Register. Since that time, there have been 3 Guidances and/or Draft Guidances published (December, 2012; December, 2015; and June, 2021) to clarify the FDA position regarding appropriate assessment and reporting of safety.
- 85. According to the FDA's December 2015 Guidance for Industry and Investigators, sponsors are required under CFR 312.32 to assess safety data from all sources, including animal studies, clinical investigations, reports in scientific literature, unpublished scientific papers and numerous other places. Specifically, the FDA wrote:

The sponsor is required to review promptly all information relevant to the safety of the drug (21 CFR 312.32(b)). During the course of drug development, adverse event information is generally reported to a sponsor by investigators conducting clinical trials; however, a sponsor may become aware of new safety information from a variety of sources, both domestic and foreign. Some examples of sources are listed as follows, but safety information from any other source would also need to be reviewed and evaluated by the sponsor.

Animal studies or in vitro studies Clinical or epidemiological investigations; Reports in the scientific literature; Unpublished scientific papers; Information presented at scientific meetings; Reports from foreign regulatory authorities; Reports from commercial marketing experience; Safety information presented at a professional meeting; Foreign spontaneous reports.

The sponsor's review should include examining data from all sources and deciding whether the information meets the criteria for expedited reporting (see section V), as well as evaluating all accumulating data at regular intervals to update safety information and to identify new safety signals. Some types of information should be sought by the sponsor as part of its continuous pharmacovigilance on the safety of the drug. For example, the *sponsor should conduct literature searches regularly* with a frequency appropriate to the drug or study design *to seek safety information* and report that information if necessary.

(Emphasis added).

- 86. Accordingly, pursuant to CFR 312.32, Immunovant was required to review the safety data from the IMVT-1401 animal studies and regularly search for and review potential safety issues with IMVT-1401 in the scientific literature and other sources.
- 87. In early clinical development phases, little may be known about safety in humans and, therefore, the results of animal studies are important for the identification of potential and/or anticipated risks. The FDA published the Guidance for Industry describing ICH M3 (R2) (Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals), stating, in pertinent part, as follows:

The development of a pharmaceutical is a stepwise process involving an evaluation of both animal and human efficacy and safety information. The goals of the nonclinical safety evaluation generally include a characterization of toxic effects with respect to target organs, dose dependence, relationship to exposure, and, when appropriate, potential reversibility. This information is used to estimate an initial safe starting dose and dose range for the human trials and to *identify parameters for clinical monitoring for potential adverse effects*. The nonclinical safety studies, although usually limited at the beginning of clinical development, should be *adequate to characterize potential adverse effects that might occur under the conditions of the clinical trial to be supported*.

88. Similarly, the FDA Guidance for Industry regarding ICH S7a (Safety Pharmacology Studies for Human Pharmaceuticals), states, in pertinent part, the following:

The objectives of safety pharmacology studies are (1) to identify undesirable pharmacodynamic properties of a substance that may have relevance to its human safety, (2) to evaluate adverse pharmacodynamic and/or pathophysiological effects of a substance observed in toxicology and/or clinical studies, and (3) to investigate the mechanism of the adverse pharmacodynamic effects observed and/or suspected. *The*

investigational plan to meet these objectives should be clearly identified and delineated.

89. The S7a Guidance document further notes:

Since pharmacological effects vary depending on the specific properties of each test substance, the studies should be selected and designed accordingly. The following factors should be considered (the list is not comprehensive).

- 1. Effects related to the therapeutic class of the test substance, since the mechanism of action may suggest specific adverse effects (e.g., proarrhythmia is a common feature of antiarrhythmic agents)
- 2. Adverse effects associated with members of the chemical or therapeutic class, but independent of the primary pharmacodynamic effects (e.g., antipsychotics and QT prolongation)
- 3. Ligand binding or enzyme assay data suggesting a potential for adverse effects
- 4. Results from previous safety pharmacology studies, from secondary pharmacodynamic studies, from toxicology studies, or from human use that warrant further investigation to establish and characterize the relevance of these findings to potential adverse effects in humans.
- 90. Thus, safety and toxicology findings from nonclinical studies are important guideposts for the development of a safety surveillance or pharmacovigilance plan. These nonclinical safety findings are particularly important in early phase clinical studies when fewer patients have been treated and direct information on tolerability in humans is available.

A Potential Risk of IMVT-1401 Was Elevated LDL and Cholesterol Levels and Cardiovascular Disease

- 91. Elevations in serum cholesterol are associated with an increased risk of vascular disease and overall mortality. Based on numerous facts existing prior to the Class Period, elevated LDL and cholesterol and therefore cardiovascular disease ("CV") were potential risks of IMVT-1401, including, without limitation, the following:
- (a) Immunovant's preclinical animal studies revealed substantial increases in cholesterol in the animals tested with IMVT-1401. According to FE, the underlying data from each

of Immunovant's pre-clinical animal studies made it abundantly clear that animals which received IMVT-1401 experienced substantially increased levels of cholesterol compared with those which did not receive IMVT-1401. In fact, FE described the increases for those animals as 200 to 300 percent higher than the control group animals which did not receive the drug.

- (b) IMVT-1401 is an FcRn inhibitor and treatment with FcRn inhibitors will potentially lower serum albumin levels. In fact, acknowledged IMVT-1401 pre-clinical and clinical trials showed reduced serum albumin levels. As a result of the decrease in serum albumin levels, serum cholesterol (total and LDL) levels may increase, as described in numerous scientific studies.
- (c) An indication for IMVT-1401 is the treatment of the thyroid condition GO. Since thyroid levels are known to impact cholesterol levels, the treatment of GO would also be expected to impact cholesterol levels. Scientific studies dating back to 1930 establish connections between thyroid hormone levels and cholesterol.
- (d) Companies developing similar compounds, including Harbour BioMed, the license holder for IMVT-1401 in Greater China, and competitor Argenx SE, tested for cholesterol, showing that those entities recognized elevated cholesterol levels was a potential risk which needed to be monitored and assessed. And Immunovant had agreements and shared information with Harbour BioMed.
- (e) Immunovant designed the protocol for the ASCEND GO-2 Phase 2b trial to monitor and assess the potential risk of elevated cholesterol levels in connection with IMVT-1401. Cholesterol was monitored in the ASCEND GO-2 Phase 2b trial because elevated LDL and cholesterol were a potential risk of IMVT-1401. That protocol was designed in 2018 and updated in February and August 2019. Even though that protocol was created before the start of the Class Period, Immunovant did not publicly disclose the details of the protocol or the fact that the clinical

trial monitored and assessed cholesterol levels until after Immunovant announced the halting of that trial at the end of the Class Period in February 2021.

Immunovant's Pre-Clinical Animal Studies Clearly Showed that IMVT-1401 Substantially Raised the Cholesterol Levels of Animals

- 92. Immunovant performed IMVT-1401 animal studies on Cynomolgus monkeys before initiating the clinical trials. Immunovant monitored and assessed the cholesterol levels of the animals tested. Those animal studies clearly showed substantial elevations in cholesterol of the animals which were given IMVT-1401.
- 93. According to FE, who worked as a senior employee in Immunovant's Non-Clinical Development group from the end of 2019 until after the Class Period, Immunovant measured the cholesterol levels in the animals which were part of the study. According to FE, the animal studies listed the cholesterol of the animals at the start of the test and at the end of the test and those results clearly showed a substantial increase in the cholesterol of the animals which received IMVT-1401. According to FE, cholesterol and triglycerides were significantly increased for animals which received IMVT-1401 compared to those that were not. FE recalled that *some animals showed 200 to 300 percent increases in cholesterol levels* compared with the control group. Furthermore, FE recalled that each of the studies revealed significant increases in cholesterol.
- 94. FE learned about the results of the IMVT-1401 animal studies in connection with FE's employment at Immunovant. According to FE, in early January 2021, patients treated with IMVT-1401 during the ASCEND GO-2 Phase 2b trial displayed increased cholesterol levels and the Principal Investigator notified IMVT-1401's clinical trial doctor regarding this issue. The Principal Investigator initiated an alert, and the Internal Monitor advised the rest of the team and Defendant Salzmann of the increased cholesterol. As a result of this issue, then-Chief Medical Officer Rita Jain directed FE to review each of Immunovant's completed preclinical animal studies to determine

whether the studies displayed an increase in total cholesterol levels in animals.

- 95. FE reviewed the toxicology studies obtained from the animals, reports, and data and observed significant increases in cholesterol levels in animals which received the drug compared to the control group. FE provided a summary of findings to the then-Chief Medical Officer Rita Jain who relayed the information to other members of senior management of Immunovant.
- 96. Since the animal studies for IMVT-1401 clearly showed the LDL and cholesterol levels of animals which received IMVT-1401 were substantially increased, there was a substantial risk that IMVT-1401 would also increase the LDL and total cholesterol levels of humans. The animal studies were conducted on Cynomolgus monkeys and therefore the effect of IMVT-1401 on those monkeys are highly relevant to the potential impact on humans. As Immunovant acknowledged in a registration statement filed on or about April 10, 2020, "Cynomolgus monkeys were selected . . . given the high degree of sequence homology to human FcRn."
- 97. According to FE, the reports for the animal studies contained detailed information showing the increases in cholesterol levels. While the reports conclusively and unambiguously showed that cholesterol levels increased for animals taking IMVT-1401, the summary portion of the reports erroneously indicated that there were only minor increases in cholesterol. Nevertheless, a reading of the full report, as opposed to a reading of just the summary, clearly showed substantial elevations in cholesterol levels for the animals.
- 98. The clear and unambiguous results from the IMVT-1401 animal studies established that elevated cholesterol levels were a potential risk of IMVT-1401. Even though there was a chance IMVT-1401 could impact humans and monkeys differently such that IMVT-1401 would not elevate cholesterol in humans, the monkey results were important datapoints and created a potential risk for humans such that IMVT-1401 clinical studies should have monitored and assessed this risk under

Good Clinical Practices and procedures.

- 99. A standard cholesterol and LDL blood test is an inexpensive and easy way to monitor a subjects' cholesterol profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides). Nevertheless, as admitted by Immunovant on February 2, 2021, unbeknownst to investors and the market, Immunovant did not monitor or assess the key potential risk of elevated cholesterol or LDL levels in clinical trials completed prior to that date.
- 100. Additionally, even though Immunovant was monitoring and assessing cholesterol and LDL levels in the ASCEND GO-2 Phase 2b trial, Immunovant never disclosed that elevated cholesterol was a potential risk of IMVT-1401. Similarly, Immunovant didn't disclose that the ASCEND GO-2 Phase 2b trial was different from the other clinical trials because it was monitoring for a key potential risk of elevated cholesterol which was not monitored in earlier clinical trials. It wasn't until Immunovant announced the halting of the ASCEND GO-2 Phase 2b trial on February 2, 2021 that it finally disclosed to investors that elevated cholesterol was a potential risk of IMVT-1401.

Numerous Studies Reported that FcRn Inhibition and Reduced Serum Albumin Levels, Such as Caused by IMVT-1401, Impact Cholesterol and Increase Risk for Cardiovascular Disease

- 101. It is widely known in the medical community that elevated lipids, in particular LDL cholesterol, are associated with cardiovascular disease, as defined in a 1992 study referred to as the Framingham Heart Study. It had also been reported in medical journals and studies for years before the start of the Class Period that a lack of FcRn and/or lower serum albumin levels impacts cholesterol levels and are associated with coronary artery disease ("CAD") and cardiovascular disease.
- 102. IMVT-1401 (also referred to as batoclimab), is a neonatal FC receptor (FcRn) inhibitor that results in a decrease in immunoglobulin ("IgG"). HanAll BioPharma, a Korean

company, developed the compound as HL-161 and later licensed rights for development of the compound to Defendant Roivant (when it was referred to as RVT-1401) and ultimately Immunovant (when it was changed to IMVT-1401). IMVT-1401 is in a class of drugs being researched by several sponsors in multiple therapeutic areas, including Argenx SE, Alexion Pharmaceuticals, and UCB. Diseases targeted in clinical trials by these sponsors, including Immunovant, include myasthenia gravis, idiopathic thrombocytopenic purpura (ITP), warm autoimmune hemolytic anemia (WAIHA), pemphigus vulgaris, thyroid eye disease (TED, also known as Grave's ophthalmopathy), chronic idiopathic demyelinating polyneuropathy (CIDP), and neuromyelitis optica.

- and Grave's disease, result from aberrant targeting of "self" by the immune system (termed autoimmune diseases). IMVT-1401 selectively binds to and inhibits the neonatal fragment crystallizable receptor, or FcRn. Neonatal Fc Receptor (FcRn) binding leads to internalization of immunoglobulin (IgG) and albumin and, in so doing, protects these compounds from degradation, thus increasing their half-lives. Reductions in circulating immunoglobulin (IgG) are postulated to improve the autoimmunity and, hence, improve the clinical condition.
- 104. While FcRn treatment may potentially be effective against the targeted medical conditions, there are also risks associated with the reduction in serum albumin levels, including the risk of cardiovascular disease and an increase in lipid levels. In addition, serum albumin reduction can lead to defective cholesterol enrichment of HDL, because SA helps transfer free cholesterol from peripheral tissues to HDL particles.
- 105. Medical and scientific studies and reports discuss that hypoalbuminemia (reduced albumin) has emerged as a potentially powerful prognostic marker in CAD and appears to have

predictive value for incidences of CV.9

106. A 2002 study by Djoussé L et al., titled *Serum albumin and risk of myocardial infarction and all-cause mortality in the Framingham Offspring Study*, (the "Framingham Offspring Study") reported that lower serum albumin concentrations were associated with an increased risk of coronary artery disease in both sexes and with all-cause mortality in women. The association between elevated lipids, in particular LDL cholesterol, and CV were clearly defined in the Framingham Offspring Study using a tercile approach to albumin levels, hazard ratios 31 observed for myocardial infarction were 1.0, 1.25, and 1.49 for men and 1.0, 1.79, and 2.12 for women, with increasing risk seen in patients with lower concentrations of serum albumin.

al., reported the results of FcRn alterations using transgenic and FcRn knockout mice and observed effects on clinical chemistry parameters. Compared with controls, *mice that lacked FcRn* (*mFcR-/; genetic modification leading to lack of FcRn*) had statistically significantly higher levels of cholesterol, LDL cholesterol and HDL cholesterol. Of the three parameters, LDL cholesterol increased in female knockout mice by approximately 66% (0.5 mmol/L in knockout vs. 0.3 mmol/L in controls) compared with control (C57BL/6J) mice. Male knockout mice were observed to have a 25% greater increase in LDL cholesterol compared with control mice (0.5 mmol/L vs. 0.4 mmol/L, respectively). In contrast to the increases in total cholesterol, LDL cholesterol and HDL cholesterol, knockout mice were noted to have highly statistically significantly lower albumin and total protein levels compared with controls.

⁹ Arques S. Serum Albumin and Cardiovascular Disease: State-Of-the-Art Review. *Ann Cardiol Angeiol (Paris)* (2020).

A knockout mouse is a laboratory mouse in which researchers have inactivated, or "knocked out," an existing gene by replacing it or disrupting it with an artificial piece of DNA.

- 108. Similar results were reported in a 2015 study titled *Albumin-deficient mouse models* for studying metabolism of human albumin and pharmacokinetics of albumin-based drugs by Roopenian et al. That study reported statistically significantly greater cholesterol levels (total, LDL, HDL) in two different knockout mice models. *Compared with controls, LDL cholesterol levels* were increased approximately two-fold in one model and four-fold in the other.
- 109. Furthermore, numerous other scientific studies and reports available before and during the Class Period discussed the connection between albumin reductions, coronary disease and cholesterol levels, including, without limitation, the following:
- (a) According to studies from 2014 and 2020, low albumin concentration is associated with increased total and LDL cholesterol levels as well as increased CV mortality risk.¹¹
- (b) According to a study from 2017, low serum albumin has been related to impairments in fibrinolysis, vasodilatory ability, and anticoagulation and increased blood viscosity and vascular permeability, all factors associated with increased CV risk.¹²
- (c) According to studies from 2001 and 2006, Microalbuminuria has been shown to be an important CV risk factor in patients with diabetes or hypertension and in the general population. ¹³ As discussed in a study from 2014, increased excretion of serum albumin via urine, even at levels not meeting the standard for microalbuminuria, has been associated with increased

Mace C, Chugh SS. Nephrotic Syndrome: Components, Connections, and Angiopoietin-Like 4-Related Therapeutics. *J Am Soc Nephrol* (2014); Arques S. Serum Albumin and Cardiovascular Disease: State-Of-the-Art Review. *Ann Cardiol Angeiol (Paris)* (2020).

¹² Chien SC, Chen CY, Lin CF, Yeh HI. Critical Appraisal of the Role of Serum Albumin in Cardiovascular Disease. *Biomark Res* (2017).

Gerstein HC, Mann JF, Yi Q, Zinman B, Dinneen SF, Hoogwerf B, et al. Albuminuria and Risk of Cardiovascular Events, Death, and Heart Failure in Diabetic and Nondiabetic Individuals. *JAMA* (2001); Stehouwer CD, Smulders YM. Microalbuminuria and Risk for Cardiovascular Disease: Analysis of Potential Mechanisms. *J Am Soc Nephrol* (2006).

incidence of all-cause and CV mortality.¹⁴

- (d) As reported in 2017, in a prospective chart study of 30,732 hospitalized patients in 10 Israeli medical wards (from January 2011-December 2013), hypoalbuminemia at admission was significantly associated with comorbid malignancy, hypertension, ischemic heart disease, and chronic kidney disease. When compared with the mean length of hospitalization for patients with normal SA concentration at admission (5±7 days), patients with mild or marked hypoalbuminemia had longer stays (7±8 days and 9±11 days, respectively) in this study. 15
- 110. These and other studies were available and understandable to highly trained scientists and professionals, such as those employed by Immunovant, Roivant, and RTW.

Thyroid Hormone Levels, Such as the Levels Impacted by Grave's Ophthalmopathy and Myasthenia Gravis, Are Connected to Cholesterol Levels

- 111. The association between thyroid hormone levels and cholesterol was also well established prior to the start of the Class Period. In fact, a study published in 1930 titled *Blood cholesterol values in hyperthyroidism and hypothyroidism their significance* in The New England Journal of Medicine by Mason, RL et al., as well as additional literature and studies, including a 2011 study titled, *Effects of thyroid dysfunction on lipid profile* in The Open Cardiovascular Medicine Journal by Rizos, CV et al., have made clear there is an inverse relationship between thyroid function and cholesterol.
- 112. Since Grave's Ophthalmopathy is a thyroid condition, and since thyroid levels are known to impact cholesterol levels, the treatment of Grave's Ophthalmopathy would also be expected to impact cholesterol levels. In fact, as reported in a 2020 study titled *Treatment of Thyroid*

Murai S, Tanaka S, Dohi Y, Kimura G, Ohte N. The Prevalence, Characteristics, and Clinical Significance of Abnormal Albuminuria in Patients With Hypertension. *Sci Rep* (2014).

Akirov A, Masri-Iraqi H, Atamna A, Shimon I. Low Albumin Levels are Associated With Mortality Risk in Hospitalized Patients. *Am J Med* (2017).

Dysfunction and Serum Lipids: A Systematic Review and Meta-Analysis in The Journal of Clinical Endocrinology & Metabolism by Kotwal, A et al., treatment of hyperthyroidism was found to increase cholesterol levels.

113. Furthermore, patients with autoimmune conditions are frequently treated for cardiovascular disease comorbidities, including myasthenia gravis. For example, in one study, approximately 60% of people with MG (140 out of 234) had abnormally high levels of lipids in the blood known as dyslipidemia, a prominent risk factor for CV. ¹⁶ It was reported in 2008 that approximately one-third of patients with MG are receiving statins for the treatment of dyslipidemia. ¹⁷

Even Though Increased Cholesterol Was a Potential Risk of IMVT-1401, Immunovant Failed to Monitor or Assess Cholesterol in Early Clinical Trials

- 114. Immunovant conducted a phase 1 trial of IMVT-1401 and the results of that study were published in the journal Neurology on April 9, 2019. Unbeknownst to investors, Immunovant failed to test for cholesterol levels during that phase 1 study. Immunovant minimized any adverse events from the phase 1 study, stating, in pertinent part, as follows: "All adverse events (AEs) were mild to moderate in severity, with no subjects requiring premature discontinuation due to AEs."
- 115. Immunovant registered four phase 2 clinical trials on clinicaltrials.gov targeting thyroid eye disease, myasthenia gravis, and warm autoimmune hemolytic anemia.
- 116. A 17-patient study of RVT-1401 treatment in patients with myasthenia gravis was initiated on May 21, 2019 and completed on December 21, 2020, comparing 680 mg RVT-1401, 340 mg RVT-1401, or placebo in a parallel fashion. The study was unblinded after 15 patients

 $^{^{16}\,\,}$ Cacho Diaz B, Flores-Gavilán P, Garcıá-Ramos G. Myasthenia Gravis and its Comorbidities. J Neurol Neurophysiol (2015).

¹⁷ Miller M. Dyslipidemia and Cardiovascular Risk: The Importance of Early Prevention. *QJM* (2009).

completed treatment and top line results were reported in a press release on August 25, 2020. The Company reported the efficacy results as being potentially "best-in-class," stating, in pertinent part, as follows: "The clinical benefits we observed in this trial provide strong support that IMVT-1401 might ultimately become a best-in-class anti-FcRn agent for MG patients..." Additionally, Immunovant stressed that IMVT-1401 was "safe," stating, in pertinent part, as follows: "Consistent with previously reported Phase 1 results, IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs), and no imbalance in headaches." Immunovant, however, failed to test for the impact of IMVT-1401 on cholesterol.

- 117. On February 29, 2020, Immunovant began the Phase 2a study of Grave's ophthalmopathy (thyroid eye disease), ASCEND-GO 1, a seven-patient study, which was completed on May 21, 2020, of RVT-1401 680 mg subcutaneously (SQ) every week for 2 weeks, followed by 340 mg SQ every week for 4 weeks. Although some study results are posted on clinicaltrials.gov, no laboratory data is described and the only adverse event in the Investigations System Organ Class (SOC) is Weight gain. One hundred percent of study participants had at least one adverse event. Lacrimation increased (2/7), Dizziness (2/7), and Fatigue (2/7) were the only adverse events reported in more than one patient. Once again, unbeknownst to investors, Immunovant did not test for changes in cholesterol.
- 118. The first time Immunovant tested for cholesterol was in the ASCEND GO-2 Phase 2b trial which was halted, as announced by the Company on February 2, 2021.
- 119. Testing for cholesterol levels is inexpensive and simply requires a blood test. Since increased cholesterol levels were a potential risk of treatment with IMVT-1401, in accordance with Good Clinical Practices and standards, Immunovant should have designed each of the phase 1 and 2

clinical trials so that each of the participants' cholesterol was tested and monitored. Unbeknownst to investors, however, Immunovant failed to test the cholesterol levels of the clinical trial participants during the IMVT-1401 Phase 1 or 2 clinical trials prior to the ASCEND GO-2 Phase 2b clinical trial.

120. On February 2, 2021, the Company admitted in a press release that cholesterol levels were not measured in prior clinical trials of IMVT-1401, stating, in pertinent part, as follows:

The Company has become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease (TED). *Cholesterol levels were not measured in prior clinical trials of IMVT-1401 in Myasthenia Gravis (MG) and in healthy subjects.* Out of an abundance of caution, the Company has decided to voluntarily pause dosing in ongoing clinical studies in both TED and in Warm Autoimmune Hemolytic Anemia, in order to inform patients, investigators, and regulators as well as to modify the monitoring program.

121. Since elevated cholesterol levels were a potential risk, and since the cholesterol levels of clinical trial participants were not being tested prior to Immunovant's ASCEND GO-2 Phase 2b clinical trial, statements about the safety and viability of IMVT-1401 prior to this time omitted material information and were misleading.

A Reasonable Investor Would Have Expected (i) IMVT-1401 Clinical Trials to Monitor Key Potential Risks, such as Cholesterol, and (ii) that Statements about IMVT-1401 Clinical Trials Were Based on an Assessment of Key Potential Risks, such as Cholesterol

122. Immunovant, as the sponsor of IMVT-1401's clinical trials, was required to adhere to FDA rules, guidelines, and Good Clinical Practices. And as set forth in the SEA, Immunovant represented it complied with FDA rules, guidelines, and Good Clinical Practices. Immunovant, therefore, was required to actively monitor and assess safety information about IMVT-1401 on an ongoing basis through a variety of methods to identify risks. According to the FDA's December 2015 Guidance for Industry and Investigators, Immunovant was required to assess safety data from all sources, including animal studies, clinical investigations, reports in scientific literature, unpublished scientific papers and numerous other places.

- 123. As a result, a reasonable investor would have expected Immunovant and the IMVT-1401 clinical trials to have adhered to FDA rules, guidelines, and Good Clinical Practices. Similarly, a reasonable investor would have expected the IMVT-1401 clinical trials to actively monitor and assess key potential risks. As alleged herein, elevated LDL and cholesterol levels and heart disease were key potential risks of IMVT-1401. Accordingly, a reasonable investor would have expected Defendants' statements about IMVT-1401, the IMVT-1401 clinical trials, and the safety of IMVT-1401, to have been based on clinical trials and clinical trial protocols which monitored and assessed all key potential risks, including elevations in cholesterol.
- trials to have monitored and assessed the key potential risk of elevated cholesterol because the dire health consequences of elevated cholesterol are widely known by public investors. High cholesterol is a common health concern among Americans. According to the Centers for Disease Control and Prevention ("CDC"), more than 95 million adults in the United States have high cholesterol levels, which puts them at increased risk for heart disease and stroke. A 2017 survey conducted by the American Heart Association found that more than 80% of American adults surveyed considered it important to manage their cholesterol levels to reduce their risk of heart disease. Additionally, the same survey found that nearly 50% of those surveyed reported having high cholesterol or being told by a healthcare professional that they had high cholesterol. Other studies have also shown that many Americans are aware of the potential risks associated with high cholesterol and are taking steps to manage their cholesterol levels. A 2015 survey conducted by the CDC found that more than 70% of adults with high cholesterol reported making changes to their diet and physical activity levels to lower their cholesterol levels.

THE SEPTEMBER 2020 OFFERING DOCUMENTS CONTAINED INACCURATE STATEMENTS OF MATERIAL FACT AND OMITTED MATERIAL INFORMATION REQUIRED TO BE DISCLOSED THEREIN

- 125. On or about August 31, 2020, Immunovant filed a Form S-1 Registration Statement with the SEC for a follow on offering of securities. On or about September 1, 2020, the Prospectus with respect to the follow-on offering, which forms part of the Registration Statement, became effective and on or about September 2, 2020 (until on or about September 4, 2020), more than 5.27 million shares of common stock of Immunovant at \$33.00 per share were sold to the public, thereby raising \$163.7 million.
- 126. In addition to the above-referenced 5.27 million shares, the September 2020 Offering included an overallotment option granted to the Underwriters to purchase up to an additional 790,513 shares of common stock and the Underwriters fully exercised this option on September 4, 2020. In total, 6,060,606 shares were sold in the September 2020 Offering at \$33.00 per share, thereby raising approximately \$200 million.
- 127. The September 2020 Offering Documents contained untrue statements of material fact and omitted material information because they failed to disclose the following facts which existed at the time:
 - (a) IMVT-1401 was less safe than represented by the Company;
- (b) There was a potential risk IMVT-1401 would substantially increase LDL and total cholesterol levels because, among other reasons:
- (i) Immunovant's animal studies for IMVT-1401 revealed a substantial increase in cholesterol for animals which received IMVT-1401;
- (ii) IMVT-1401 was in a class of drug which lowered serum albumin levels, and medical journals and studies reported that low serum albumin levels increase LDL and total cholesterol levels;

- (iii) Thyroid conditions which were indications for IMVT-1401, such as Grave's Ophthalmopathy and myasthenia gravis, are known to reduce cholesterol, so if IMVT-1401 is successful in treating the underlying thyroid condition, it should be expected that cholesterol would increase;
- (iv) Other companies researching the same class of drug apparently recognized this risk because they tested cholesterol levels;
- (v) Immunovant monitored cholesterol in the ASCEND GO-2 Phase 2b trial because it was a potential risk;
- (c) Immunovant's statements about IMVT-1401's clinical trials, including about safety results, failed to incorporate an assessment of the potential risk of elevated cholesterol levels;
- (d) Immunovant failed to follow FDA regulations and Good Clinical Practices in connection with IMVT-1401 because it failed to perform ongoing surveillance of the adverse events and suspected adverse reactions of elevated LDL and total cholesterol levels;
- (e) The undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or disrupt IMVT-1401's prospects for commercial viability and profitability; and
- (f) Immunovant's business, operations and financial condition were not as represented.
- 128. Specifically, the September 2020 Offering Documents contained untrue statements of material fact and omitted material information concerning (i) IMVT-1401's clinical trials; (ii) the potential negative impact of albumin reductions, (iii) Immunovant's compliance with Good Clinical Practices, and (iv) IMVT's nonclinical animal studies.

Statements Concerning IMVT-1401's Clinical Trials

- 129. The September 2020 Offering Documents highlighted the large market potential for IMVT-1401 and represented the pre-clinical and clinical trials for IMVT-1401 were proceeding extremely well. The September 2020 Offering Documents represented the IMVT-1401 pre-clinical and clinical trials had shown the efficacy of IMVT-1401 without any serious adverse events or side effects.
- 130. The September 2020 Offering Documents discussed the large potential markets for IMVT-1401, stating in pertinent part, as follows:

We are developing IMVT-1401 as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule. As a result of our rational design, we believe that IMVT-1401, if approved for commercial sale, would be differentiated from currently available, more invasive treatments for advanced IgG-mediated autoimmune diseases (e.g., MG, TED, WAIHA, idiopathic thrombocytopenic purpura, pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy, bullous pemphigoid, neuromyelitis optica, pemphigus foliaceus, Guillain-Barré syndrome and PLA2R+ membranous nephropathy). *In 2019, these diseases had an aggregate prevalence of approximately 243,000 patients in the United States and 388,000 patients in Europe*.

131. The September 2020 Offering Documents made it appear as if IMVT-1401's clinical trials were progressing smoothly, stating in pertinent part, as follows:

In August 2019, we initiated dosing in our ASCEND MG trial, a Phase 2a clinical trial in patients with MG. We announced topline results from this trial in August 2020. In May 2019, we initiated dosing in our ASCEND GO-1 trial, a Phase 2a clinical trial in Canada in patients with TED. We announced initial results from this trial in March 2020. Enrollment is ongoing in our ASCEND GO-2 trial, a Phase 2b clinical trial for TED in the United States, Canada and Europe. We currently remain on track to report initial results from our ASCEND GO-2 trial in the first half of calendar year 2021. In November 2019, we submitted an IND to the DA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the high-dose cohort of this Phase 2a trial of IMVT-1401 in patients with WAIHA in the first quarter of calendar year 2021. In addition, we intend to announce three new indications for IMVT-1401 over the next 12 months.

132. The September 2020 Offering Documents discussed IMVT-1401's clinical trial

results and represented that IMVT-1401 was safe, "well-tolerated," and without adverse events ("AEs") or "discontinuations due to AEs."

133. The September 2020 Offering Documents reported on the "Safety Data" from a multi-part, placebo-controlled Phase 1 clinical trial, stating in pertinent part, as follows:

In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 treatment-emergent AEs and no discontinuations due to AEs.... To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. There have been no treatment-related serious AEs reported.

134. The September 2020 Offering Documents described Immunovant and its development and testing of IMVT-1401, stating, in pertinent part, as follows:

In a Phase 1 clinical trial, IMVT-1401 has demonstrated dose-dependent reductions in serum levels of IgG antibodies and was well-tolerated following subcutaneous and intravenous administration to healthy volunteers. In addition, completed clinical trials of other anti-FcRn antibodies have produced positive proof-of-concept activity in multiple IgG-mediated autoimmune diseases. We believe that these data support FcRn as a viable pharmacologic target with the potential to address multiple IgG-mediated autoimmune diseases. We intend to develop IMVT-1401 as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule.

135. The statements referenced above in ¶133 and 134 were inaccurate statements of material fact and misleading because they failed to disclose elevated cholesterol was a potential risk of IMVT-1401. Stating that "IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 treatment-emergent AEs and no discontinuations due to AEs" was misleading because elevated LDL and cholesterol levels were potential risks of IMVT-1401 and Immunovant has not assessed or evaluated that potential AE. A reasonable investor would have expected Defendants' statements to have been based on clinical trials which monitored all key anticipated risks, when that was not what transpired. And the September 2020 Offering Documents lacked a reasonable basis to assert IMVT-1401 was "well-tolerated," "with no Grade 3 or Grade 4 treatment-emergent AEs," and without "serious AEs" because there was a risk that patients receiving IMVT-1401 experienced

elevated cholesterol levels. Additionally, a reasonable investor would have expected the September 2020 Offering Documents to have disclosed that statements about safety did not include an assessment of a key risk.

136. Additionally, the September 2020 Offering Documents provided tables of a "summary of the most commonly reported AEs" and the "Most Common Adverse Events Reported in Phase 1 Clinical Trial of IMVT-1401," but elevated LDL or cholesterol levels were not included in those tables. The tables were incomplete and misleading because they failed to acknowledge the potential risk of elevated cholesterol, which could have presented as one of the most "commonly reported AEs" if it had been monitored. They were also misleading because they failed to notify investors the IMVT-1401 clinical trials had not monitored cholesterol.

137. The September 2020 Offering Documents represented positive facts about prior and ongoing trials of IMVT-1401 but failed to disclose the risk of increased cholesterol or that the Company hadn't even tested for cholesterol in completed trials, stating, in pertinent part, as follows:

Phase 1 Clinical Trials of IMVT-1401 in Healthy Volunteers

We have completed a multi-part, placebo-controlled Phase 1 clinical trial involving 99 healthy volunteers in Australia and Canada, administering IMVT-1401 both as an intravenous infusion and as a subcutaneous injection. In this trial, 77 subjects received at least one dose of IMVT-1401 and 22 subjects received placebo.

* * *

The IgG reductions we observed in this multi-part, placebo-controlled Phase 1 clinical trial support the continued development of IMVT-1401.

Safety Data

In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo. To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. There have been no

treatment-related serious AEs reported.

138. The statements referenced above in ¶137 were each inaccurate statements of material fact when made because they discussed positive aspects of the IMVT-1401 clinical trials but omitted to disclose negative information, such as that elevations in cholesterol were a potential risk of IMVT-1401. The statement "observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was inaccurate and misleading because Immunovant had observed substantially elevated cholesterol levels in the animal studies and there was a potential risk that there would also be substantially elevated levels in humans. The statements about a lack of AEs being related to IMVT-1401 were inaccurate and misleading because implicit in the statements was that the IMVT-1401 clinical trials monitored all key risks, such as the risk of elevations in cholesterol. Additionally, the September 2020 Offering Documents lacked a reasonable basis to represent there had been "no treatment-related serious AEs" because patients may have experienced elevated cholesterol.

139. The September 2020 Offering Documents discussed the results of ASCEND clinical trials of IMVT-1401, stating, in pertinent part, as follows:

ASCEND MG Trial

In August 2019, we initiated dosing in our ASCEND MG clinical trial. The ASCEND MG trial is a multi-center, randomized, placebo-controlled Phase 2a clinical trial designed to evaluate the safety, tolerability, pharmacodynamics, and efficacy of IMVT-1401 in patients with moderate-to-severe MG... The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401 and measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG... Consistent with previously reported Phase 1 results, IMVT-1401 was observed to be well-tolerated with no SAEs reported, no withdrawals due to AEs, and no imbalance in headaches.

* * *

ASCEND GO-1 Trial

In May 2019, we initiated dosing in our ASCEND GO-1 trial, an open label single-

arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with TED. We announced initial results from this trial in March 2020... The primary endpoints of this trial are safety and tolerability of IMVT-1401 over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses... The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. Mean albumin reduction from baseline to end of treatment was 24%. All AEs were mild or moderate and there were no headaches reported.

- 140. The statements referenced above in ¶139 were each inaccurate statements of material fact when made because they failed to disclose that a key potential risk of IMVT-1401 was elevated cholesterol and made it appear as if IMVT-1401 was safer than it was. The statements, the ASCEND MG trial was "designed to evaluate...safety, tolerability," the ASCEND MG primary endpoints...are...safety and tolerability," and the ASCEND GO-1 "primary endpoints...are safety and tolerability," were each inaccurate and misleading because those clinical trials did not assess or monitor the key potential risk of elevated cholesterol levels. Additionally, the statements referenced above in ¶139 that "IMVT-1401 was observed to be well-tolerated with no SAEs...no withdrawals due to AEs" and that the "safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401" were inaccurate and misleading because a reasonable investor would have expected those statements to have been based on an assessment of all key potential risks, including elevated cholesterol, when that was not what occurred. The statement "[a]Il AEs were mild or moderate" was inaccurate and misleading because Immunovant failed to test for the potential risk of elevated cholesterol levels, so "all AEs" did not include the assessment of a key potential risk.
- 141. The September 2020 Offering Documents, in comparing IMVT-1401 with competing products, described there was a lack of "safe and effective treatment options for patients suffering from autoimmune diseases" and that IMVT-1401 compared favorably because it had already shown itself to be a safe solution for this market need, and stated, in pertinent part, as follows:

Unfortunately, safe and effective treatment options for patients suffering from autoimmune diseases are lacking. Currently available treatments are generally limited to corticosteroids and immunosuppressants in early-stage disease and intravenous immunoglobulin, or IVIg, or plasma exchange in later-stage disease. These approaches often fail to address patients' needs since they are limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.

* * *

FcRn plays a pivotal role in preventing the degradation of IgG antibodies. The physiologic function of FcRn is to modulate the catabolism of IgG antibodies, and inhibition of FcRn, such as through use of an anti-FcRn antibody, has been shown to reduce levels of pathogenic IgG antibodies. Completed clinical trials of Immunovant and other anti-FcRn antibodies in IgG-mediated autoimmune diseases have generated promising results, suggesting that FcRn is a therapeutically important pharmacologic target to reduce levels of these disease-causing IgG antibodies.

In several nonclinical studies and a multi-part Phase 1 clinical trial in healthy volunteers, intravenous and subcutaneous delivery of IMVT-1401 demonstrated dose-dependent IgG antibody reductions and was observed to be well tolerated. In the highest dose cohort from the multiple-ascending dose portion of the Phase 1 clinical trial, four weekly subcutaneous administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, with a standard deviation of 2%. IMVT-1401 was generally well-tolerated in this study, and the majority of adverse events, or AEs, reported were mild or moderate. Injection site reactions were similar between IMVT-1401 and placebo arms.

142. The statements referenced above in ¶141 were inaccurate statements of material fact and misleading because they created the inaccurate impression that IMVT-1401 was a safe and effective alternative for drugs targeting the same areas as IMVT-1401 even though elevated cholesterol was a key potential risk and its trial results did not include an assessment of this potential risk. The September 2020 Offering Documents focused on positive aspects of the test results of IMVT-1401 but failed to disclose the potential risk of elevated cholesterol and cardiovascular disease. The statements were materially inaccurate because they made favorable comments about the relative safety of IMVT-1401 but failed to disclose that there was a potential risk of heart disease and elevated cholesterol levels.

- 143. Additionally, the statements referenced above in ¶141 that IMVT-1401 "was generally well-tolerated in this study, and the majority of adverse events, or AEs, reported were mild or moderate" were materially untrue and misleading because implicit in those statements was that key potential risks were assessed. As alleged herein, however, the IMVT-1401 clinical trials did not assess cholesterol levels so this potential risk could have presented itself during those trials so the statements made it appear as if IMVT-1401 was safer than it actually was. The statement, "[c]ompleted clinical trials of Immunovant and other anti-FcRn antibodies in IgG-mediated autoimmune diseases have generated promising results" was also inaccurate and misleading because those results did not include an assessment of cholesterol. Finally, the statement that "several nonclinical studies and a multi-part Phase 1 clinical trial" was "observed to be well tolerated" was untrue because the animal studies revealed substantial increases in cholesterol, and it was unknown whether the "Phase 1 clinical trial" was "well tolerated" because Immunovant failed to test cholesterol levels.
- 144. The September 2020 Offering Documents discussed the ASCEND GO-2 Phase 2b trial, stating, in pertinent part, as follows:

ASCEND GO-2 Trial

In October 2019, we initiated dosing in our ASCEND GO-2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 patients with moderate-to-severe active TED with confirmed autoantibodies to TSHR. The ASCEND GO-2 trial explores the potential of IMVT-1401 to improve proptosis and assesses the safety and tolerability of IMVT-1401 in this population. Patients in this trial will be treated with one of three doses of IMVT-1401 (680 mg, 340 mg or 255 mg) or placebo administered weekly by subcutaneous injection for 12 weeks. The primary endpoints of this trial are...safety and tolerability... We currently remain on track to report initial results from our ASCEND GO-2 trial in the first half of calendar year 2021.

145. The statements referenced above in ¶144 were materially inaccurate and misleading because even though the ASCEND GO-2 Phase 2b trial was described with the exact same language

of "primary endpoints" being "safety and tolerability," as other clinical trials, the assessment of safety and tolerability during the ASCEND GO-2 Phase 2b trial was very different from other clinical trials because it assessed cholesterol levels. Additionally, the statement "remain on track to report initial results" was misleading because it created the inaccurate impression the ASCEND GO-2 Phase 2b trial was simply another clinical trial in a long line of clinical trials. Unbeknownst to investors, the ASCEND GO-2 Phase 2b trial was assessing cholesterol so there was a heightened risk elevations in cholesterol would be identified which would likely result in a disruption and delay of the IMVT-1401 clinical trial program.

Statements Concerning the Potential Negative Impact of Albumin Reductions

146. The September 2020 Offering Documents acknowledged that IMVT-1401 clinical trials revealed reductions in serum albumin in patients during a multi-part, placebo-controlled Phase 1 clinical trial, but minimized the negative implications of the albumin reductions and failed to disclose the potential risks associated with serum albumin reductions as set forth in numerous scientific studies and journals, stating, in pertinent part, as follows:

Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts.... These reductions were not associated with any AEs or clinical symptoms and did not lead to any study discontinuations. The clinical relevance of isolated, mild hypoalbuminemia is unknown, however, a hereditary syndrome associated with deficient albumin production has been described (Congenital Analbumenia). In this syndrome, despite extremely low or absent levels of albumin, those affected have only mild symptoms, including fatigue, low blood pressure and edema. It is believed that compensatory mechanisms through the production of other proteins may allow for relatively normal physiologic function in this population.

147. The statements referenced above in ¶146 were inaccurate statements of material fact and misleading because they minimized the impact of albumin reductions. Contrary to the statement "clinical relevance of isolated, mild hypoaluminemia is unknown," medical and scientific studies and reports discussed that hypoalbuminemia has emerged as a potentially powerful prognostic

marker in coronary artery disease and elevates cholesterol. Additionally, the reference to "mild" hypoalbuminemia was misleading because the albumin reductions observed in the IMVT-1401 trial were more substantial than "mild." While the phase 1 clinical trial may not have *revealed* "any AEs or clinical symptoms," that trial had not monitored or assessed the likely adverse event of elevated LDL and cholesterol levels. As a result, the September 2020 Offering Documents lacked a reasonable basis to represent the "reductions were not associated with any AEs" because the reductions could have been - and likely were - associated with elevated LDL and cholesterol levels. Furthermore, the statement gave the false impression the clinical trial tested for all key potential risks, as required under FDA rules and regulations and good clinical practices, when this was not true.

148. Furthermore, the statements referenced above in ¶146 minimized the potential negative consequences of albumin reductions by characterizing them as "mild" and "reversible" and by discussing them only in the context of an unrelated and extremely rare condition known as Congenital Analbumenia, which causes, according to Immunovant's SEC filings, "only mild symptoms."

Statements Concerning IMVT's Nonclinical Animal Studies

149. The September 2020 Offering Documents discussed pre-clinical trials of IMVT-1401, stating, in pertinent part, as follows:

Nonclinical Studies of IMVT-1401

Cynomolgus monkeys were selected as the primary species for nonclinical testing, given the high degree of sequence homology to human FcRn and IMVT-1401's strong binding affinity for monkey FcRn. Our partner, HanAll, completed five nonclinical studies of IMVT-1401 (referred as HL161BKN for the purposes of these studies) in cynomolgus monkeys.

* * *

Importantly from the 26-week toxicity study, based on the overall toxicity profile

following 26 weeks of SC injections (200 mg/kg/week), the No-Observed-Adverse-Effect-Level (NOAEL) of IMVT-1401 following SC injection was concluded to be 100 mg/kg/dose or 200 mg/kg/week; we estimate that this represents an approximate 3-fold safety margin (100 mg/kg/dose) when compared to the planned clinical dose of 680 mg/dose taking into account allometric corrections between monkeys and humans. Moreover, the estimated safety margin is increased to approximately 6-fold when considering IMVT-1401 was administered twice per week at 200 mg/kg/week. *Overall, in these nonclinical studies, there was a robust PK/TK and PD correlation in cynomolgus monkeys after removing the confounding element of ADA*. The immunogenicity response to human proteins generated in nonclinical species is generally not predictive of that in the human. *Nevertheless, subjects in clinical trials with IMVT-1401 will be carefully monitored for any AEs, including those related to immunogenicity*.

150. The statements referenced above in ¶149 were each inaccurate statements of material fact when made because they focused on the positive aspects of the preclinical animal studies but failed to disclose that Immunovant's animal studies revealed substantial increases in cholesterol for animals taking IMVT-1401. Additionally, the statement "subjects in clinical trials with IMVT-1401 will be carefully monitored for any AEs, including those related to immunogenicity" was inaccurate because even though the animal studies showed increases in cholesterol, IMVT-1401's early clinical trials failed to "carefully monitor" for the AE of elevated LDL and cholesterol levels.

Statements Concerning Compliance with Good Clinical Practices

process requires the "performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, *Good Clinical Practice, or GCP, and other clinical-trial related regulations and guidance to evaluate the safety*, purity and potency of the proposed biologic product candidate for each proposed indication." The September 2020 Offering Documents also discussed that the failure of third parties to comply with the "the FDA's Good Clinical Practice, or GCP" could "have an adverse effect on Immunovant's results of operations." These statements created the untrue perception that Immunovant's clinical trials complied with Good Clinical Practices and procedures. Contrary to those statements, IMVT-1401 clinical trials failed to comply

with Good Clinical Practices because they had not monitored or assessed the key potential risk of elevated LDL or cholesterol levels.

The September 2020 Offering Documents Omitted Known Trends, Events and Uncertainties that Were Impacting, and Would Impact, the Company's Financial Results

- 152. Pursuant to Item 10 of Form S-11, registrants are required to provide the information required by Item 303 of Regulation S-K [17 C.F.R. §229.303], including any known trends, events or uncertainties that have caused or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. This includes descriptions and amounts of matters that have had a material impact on reported operations, as well as matters that are reasonably likely based on management's assessment to have a material impact on future operations.
- 153. The increase in cholesterol levels in animals, the fact that it was an anticipated risk that IMVT-1401 would increase cholesterol levels in patients, that none of the completed clinical studies had yet tested cholesterol levels, and that the ASCEND GO-2 Phase 2b trial was the first clinical trial to test for cholesterol levels, were known events and uncertainties that were having and were reasonably likely to have an impact on the Company's continuing operations and therefore were required to be disclosed in the September 2020 Offering Documents, but were not.
- 154. In 1989, the SEC issued an interpretive release on Item 303 and the disclosure required under the regulation. *See* Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A"), SEC Release No. 6835, 1989 WL 1092885, at *1 (May 18, 1989) (hereinafter referred to as "1989 Interpretive Release"). In the 1989 Interpretive Release, the SEC stated that:

Required disclosure is based on currently known trends, events and uncertainties that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract. . . . A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects

on the registrant's financial condition or results of operation.

Id. at *4.

155. Furthermore, the 1989 Interpretive Release provided the following test to determine if disclosure under Item 303(a) is required:

Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:

- (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
- (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

Id. at *6.

"existing cash balance as of June 30, 2020 . . . we expect to be able to fund our operating expenses and capital expenditure requirements into the first half of 2022." It was a known trend and uncertainty that the IMVT-1401 animal studies had revealed substantial elevations in cholesterol and that a key potential risk of IMVT-1401 was elevated cholesterol. It was also a known trend and uncertainty that albumin reductions were described in medical journals and studies to elevate cholesterol and that IMVT-1401 may elevate cholesterol. Additionally, since the ASCEND GO-2 Phase 2b trial was the first clinical trial to monitor and assess cholesterol, and since elevated cholesterol was a potential risk of IMVT-1401, it was a known uncertainty that the clinical trial schedule for IMVT-1401 could be disrupted, and that additional expenditures would be required, if the ASCEND GO-2 Phase 2b trial revealed elevations in cholesterol. If elevations in cholesterol were observed during the ASCEND GO-2 Phase 2b trial, those results would likely materially

impact Immunovant's financial condition or results of operation because Immunovant would need to materially adjust the clinical trial schedule and capital expenditures.

The September 2020 Offering Documents Omitted to Include Significant Factors that Made the Offering Risky

- 157. Pursuant to Item 3 of Form S-11, the September 2020 Offering Documents were required to furnish the information pursuant to Item 105 of Regulation S-K [17 C.F.R. §229.105], including, among other things, "a discussion of the material factors that make an investment in the registrant or offering speculative or risky," including the following:
 - (a) IMVT-1401 was less safe than represented by the Company;
- (b) There was a potential risk that IMVT-1401 would substantially increase LDL and total cholesterol levels because, among other reasons:
- (i) Immunovant's animal studies for IMVT-1401 revealed a substantial increase in cholesterol for animals which received IMVT-1401;
- (ii) IMVT-1401 was in a class of drug which lowered serum albumin levels, and medical journals and studies reported that low serum albumin levels increase LDL and total cholesterol levels;
- (iii) Thyroid conditions which were indications for IMVT-1401, such as Grave's Ophthalmopathy and myasthenia gravis, are known to reduce cholesterol, so if IMVT-1401 is successful in treating the underlying thyroid condition, it should be expected that cholesterol would increase;
- (iv) Other companies researching the same class of drug apparently recognized this risk because they tested cholesterol levels;
- (v) Immunovant monitored cholesterol in the ASCEND GO-2 Phase 2b trial because it was a potential risk;

- (c) Immunovant's statements about IMVT-1401's clinical trials, including about safety results, failed to incorporate an assessment of the potential risk of elevated cholesterol levels;
- (d) Immunovant failed to follow FDA regulations and Good Clinical Practices in connection with IMVT-1401 because it failed to perform ongoing surveillance of the adverse events and suspected adverse reactions of elevated LDL and total cholesterol levels;
- (e) The undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or derail IMVT-1401's prospects for commercial viability and profitability; and
- (f) Immunovant's business, operations and financial condition were not as represented.

Any Purported Risk Warnings in the September 2020 Offering Documents Were Inadequate

- 158. Even though the September 2020 Offering Documents contained purported risk warnings or warnings that certain statements may be forward-looking, they did not adequately warn investors about the untrue facts, misrepresentations and omissions alleged herein. These risk warnings: (i) were untrue, incorrect or misleading as a matter of current or historical fact; and/or (ii) were not meaningful because, among other things, they were vague, boilerplate and did not adequately warn of the true risks of investing in Immunovant.
- 159. The September 2020 Offering Documents purported to warn about safety or adverse events delaying clinical trials, and stated, in pertinent part, as follows:

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of a BLA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit negative safety signals in later stage clinical trials that they did not exhibit in nonclinical or earlier-stage clinical trials...

The commencement and completion of clinical trials may be delayed by several factors, including: ...

• unforeseen safety issues, or subjects experiencing severe or unexpected adverse events, or AEs;

* * *

Our product candidate may cause adverse events or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

Adverse events associated with our product candidate in our clinical trials could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

- 160. The statements referenced above in ¶159 were false or misleading as a matter of current or historical fact and/or were not meaningful because the September 2020 Offering Documents omitted to disclose that facts existed at the time of the statements indicating elevated cholesterol was a potential risk of IMVT-1401 and that those statements did not warn investors of that potential risk and its ramifications.
- 161. The September 2020 Offering Documents purported to warn that the Company evaluated IMVT-1401 in nonclinical studies and early-stage clinical trials, and stated, in pertinent part, as follows:

The results of our nonclinical and clinical trials may not support our proposed claims for our product candidate, or regulatory approval on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results.

* * *

We are at an early stage in our development efforts for IMVT-1401 and we may not be able to successfully develop and commercialize our product candidate on a timely basis or at all.

We have not yet succeeded and may never succeed in demonstrating efficacy and safety for IMVT-1401 in pivotal clinical trials or in obtaining marketing approval

thereafter. For example, although we and our licensing partner have evaluated IMVT-1401 nonclinical studies and in early-stage clinical trials, we have not yet advanced IMVT-1401 into a large-scale, pivotal clinical trial for any indication. Positive results from our early-stage clinical trials are not necessarily predictive of the results of our planned clinical trials of IMVT-1401.

- 162. The statements referenced above in ¶161 were false or misleading as a matter of current or historical fact and/or were not meaningful because the September 2020 Offering Documents omitted to disclose Immunovant's clinical trials of IMVT-1401 revealed substantial elevations in cholesterol of animals and that a potential risk of IMVT-1401 was elevated cholesterol.
- 163. The September 2020 Offering Documents purported to warn that safety issues in IMVT-1401 would have a material adverse effect on business, and stated, in pertinent part, as follows:

Our business is heavily dependent on the successful development, regulatory approval and commercialization of our sole product candidate, IMVT-1401.

* * *

In addition, if our product candidate encounters safety or efficacy problems, developmental delays, regulatory issues, supply issues, or other problems in one of our target indications, our development plans for our product candidate could be significantly harmed in other indications, which would have a material adverse effect on our business.

164. The statements referenced above in ¶163 were false or misleading as a matter of current or historical fact and/or were not meaningful because the September 2020 Offering Documents omitted to disclose a potential risk of IMVT-1401 was elevated cholesterol.

Immunovant's Updated Cautionary Language After the Class Period Illustrates the Inadequacies of Its Class Period Cautionary Language

165. After the end of the Class Period, Immuovant substantially modified its public statements and risk warnings about IMVT-1401. These changes illustrate both the significance of the elevations in cholesterol on IMVT-1401 and that Immunovant's disclosures and purported cautionary language were not adequate during the Class Period.

- 166. Immunovant's Form 10-K for the fiscal year ended March 31, 2022, as filed with the SEC on June 8, 2022, stated in pertinent part, as follows:
 - Batoclimab has caused and may cause adverse events, including elevated lipid levels or decreased albumin levels among treated patients, or have other properties that could delay or prevent its regulatory approval, cause us to further suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance.

Batoclimab has caused and may cause adverse events ("AEs"), including
elevated lipid levels or decreased albumin levels among treated patients, or
have other properties that could delay or prevent its regulatory approval,
cause us to further suspend or discontinue clinical trials, abandon further
development or limit the scope of any approved label or market acceptance.

 Even if we are able to continue clinical development of batoclimab with such risk mitigations, any future approval and marketing would suffer from the risks of potential long-term lipid and albumin changes and potential impact of mitigating measures, including, among others, limited indication, monitoring, a REMS, potential additional safety studies and other adverse labeling.

• The FDA may also find that the benefits of batoclimab in any of our target indications do not outweigh its risks, including the risks associated with elevated lipid levels and lower albumin levels, in a manner sufficient to grant regulatory approval.

- The commencement and completion of clinical trials may be delayed by several factors, including:
 - o continuation of *previously identified safety issues despite our program-wide safety strategy* to characterize the safety profile of batoclimab in response to the previously reported change in albumin and lipids;

• If results from our Phase 1 and Phase 2 clinical trials cannot be replicated, or

if the increase in total cholesterol and LDL levels or total albumin reductions observed in our Phase 2 clinical trial of batoclimab cannot be mitigated, we may be unable to successfully develop, obtain regulatory approval for and commercialize batoclimab for the treatment of MG, TED and WAIHA or any other autoimmune indication.

The Company's Stock Declines

167. On February 2, 2021, Immunovant issued a press release "announc[ing] a voluntary pause in clinical dosing of IMVT-1401." Specifically, that press release stated, in relevant part:

The Company has become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease (TED). Cholesterol levels were not measured in prior clinical trials of IMVT-1401 in Myasthenia Gravis (MG) and in healthy subjects. Out of an abundance of caution, the Company has decided to voluntarily pause dosing in ongoing clinical studies in both TED and in Warm Autoimmune Hemolytic Anemia, in order to inform patients, investigators, and regulators as well as to modify the monitoring program.

ASCEND GO-2 is a randomized, placebo-controlled trial in TED evaluating different doses, each given weekly for 12 weeks. In this study, cholesterol parameters are assessed at baseline, at twelve weeks, and at week 20 following eight weeks off drug. Based on preliminary, unblinded data from about 40 patients through week 12, mean LDL cholesterol at week 12 was increased by approximately 65% in the 680mg dose group, by approximately 40% in the 340mg dose group, and did not increase in the control group. Average HDL and triglyceride levels increased to a much lesser degree. For context, commercially available statins report a reduction in LDL cholesterol between 27-60%. At the twenty-week timepoint, average LDL levels had declined to baseline or lower in the 680mg dose group, in the 340mg dose group, and in the control group. No serious cardiovascular events have been reported to date in IMVT-1401 clinical trials.

Harbour BioMed, the license holder for 1401 in Greater China, has informed Immunovant that based on their preliminary review of blinded data in their ongoing clinical studies in Chinese patients with MG and Idiopathic Thrombocytopenic Purpura, similar increases in cholesterol have not been observed. The Company is not aware whether trials involving other anti-FcRn agents in development have performed detailed assessments of lipid parameters.

The Company will work closely with regulators and scientific experts to characterize the detailed profile of these lipid changes and to understand the mechanism of these changes across indications. After discussion and agreement with regulators regarding protocol modifications, the Company intends to continue to pursue development of IMVT-1401.

Immunovant will host a conference call on Tuesday, February 2 at 8:00am EST. Following prepared remarks, the call will include a live question-and-answer session for the investment community.

168. That same day, Immunovant hosted a Special Call for analysts and investors to discuss the Company's press release and the halting of the IMVT-1401 studies (the "2/2/21 Conf Call"). During the 2/2/21 Conf Call, Defendant Salzmann discussed the voluntary pause in clinical dosing of IMVT-1401, stating, in pertinent part, as follows:

Immunovant is voluntarily pausing dosing in our clinical trials of IMVT-1401. We just recently became aware of a physiological signal consisting of elevated total cholesterol and LDL in IMVT-1401-treated patients in our thyroid eye disease Phase IIb trial. We decided to pause dosing in our active clinical trials so that we could carefully review the data, so that we could notify regulators and investigators and so that we could make modifications to the patient consent form as well as to the lipid monitoring and management parameters in our program.

169. During the 2/2/21 Conf Call, Defendant Salzmann responded to a question about the declines in albumin, stating, in pertinent part, as follows:

So for the 680-milligram dose in the Phase I trial and in the myasthenia gravis trial, we saw reductions in albumin of 25% to 30%. That's the average for the group. And in the 340-milligram dosage arm in the Phase I trial as well as in the myasthenia trial, we saw reductions in the 15%-20%-range group average mean change from baseline.

170. During the 2/2/21 Conf Call, Defendant Salzmann acknowledged that an increase in cholesterol could be associated with the treatment of the underlying TED condition, stating, in pertinent part, as follows:

Samuel Evan Slutsky - LifeSci Capital, LLC, Research Division - Senior Research Analyst

Okay. And then, I guess, in terms of TED specifically. Since they have hyperthyroidism, which could be associated, I guess, with LDL, is it possible that the increases could be due to normalizing of thyroid function? Maybe it's overshooting. Or kind of what's your take on that since it's kind of specific to TED, that hyperthyroid is an aspect?

Peter Salzmann - Immunovant, Inc. - CEO & Director

Yes, I think that's a plausible hypothesis and one we're definitely going to look into.

The patients are not hyperthyroid at enrollment. So they do have obviously the presence of thyroid-stimulating auto antibodies. And then their hyperthyroidism is controlled in one way or another, and there's a requirement that they'd be relatively euthyroid. They can't be more than 50% hyper or hypothyroid, based on their TSH and T3 levels. So there's some variability when they enter. And as I mentioned earlier, we did collect TSH and T3 and T4 levels, and so we have a chance and opportunity to look for correlations there, which we'll be doing.

171. On the 2/2/21 Conf Call, Defendant Salzmann acknowledged the importance of the cholesterol readings to the IMVT-1401 clinical studies, stating, in pertinent part, as follows:

So this is the excursions in cholesterol was something that we just recently became aware of in our data set. And when we became aware of it, we dug into it and quickly and then made a decision to unblind the data set and presenting the information that we found to regulators and investigators today and as well as investors.

- 172. Following the Company's February 2, 2021 announcement, the price of Immunovant stock collapsed from a closing price of \$43.30 per share on February 1, 2021 to a closing price of \$25.08 per share on February 2, 2021, a one day decline of \$18.22 per share, or 42.08%, on extremely heavy trading volume of 11.76 million shares. Immunovant stock continued to decline for the next several days, and by February 16, 2021 Immunovant stock traded at \$16.17 per share.
- 173. An article titled *Stock Alert: Immunovant Falls 43% After Voluntary Pause in IMVT-1401 Clinical Dosing* by NASDAQ published on February 2, 2021, stated, in pertinent part, as follows:
 - (RTTNews) Shares of Immunovant, Inc. (IMVT), a clinical-stage biopharmaceutical company, are tumbling 43 percent or \$18.62 in Tuesday's morning trade at \$24.68. Tuesday, Immunovant announced a voluntary pause of dosing in its ongoing clinical trials for IMVT-1401. The company said it has become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease or TED. Cholesterol levels were not measured in prior clinical trials of IMVT-1401 in Myasthenia Gravis (MG) and in healthy subjects.
- 174. An article titled *Immunovant stock loses half its value after pausing dosing in trial of thyroid eye disease treatment* by Market Watch published on February 2, 2021, stated, in pertinent

part, as follows:

Shares of Immunovant...plunged 49.8% to pace all premarket losers Tuesday, after the biopharmaceutical company said it has paused dosing in its phase 2b trial for IMVT-1401, a treatment for thyroid eye disease (TED). The company said it voluntarily decided to pause dosing, "out of an abundance of caution," after it became aware of a physiological signal consisting of elevated total cholesterol, as cholesterol levels were not measured in prior trials. The company said it is pausing dosing in order to inform patients, investigators and regulators, as well as to modify the monitoring program.

175. An article titled *Why Immunovant Stock Dropped Today* by The Motley Fool published on February 2, 2021, stated, in pertinent part, as follows:

Shares of Immunovant...were down by 43.2% as of 2:57 p.m. EST on Tuesday, after plunging by as much as 48% earlier in the day. The losses came after Immunovant announced an update regarding one of its ongoing clinical trials.

* * *

The market doesn't like uncertainty, and while we don't know for sure whether the higher LDL observed in patients taking IMVT-1401 after 12 weeks was due to the experimental medicine, today's news was enough to scare off investors. And considering IMVT-1401 is Immunovant's only pipeline candidate at the moment (the company has no products on the market), staying far away from this healthcare stock seems like the right move.

176. An analyst report on the Company by UBS dated February 5, 2021, stated, in pertinent part, as follows:

LDL issue likely TED specific but sentiment damaged - value here for the patient

Following IMVT's update re raised LDL levels in IMVT-1401-treated patients in the TED trial, we are lowering our PT to \$33 (from \$67). Our work-to-date (see inside) indicates this issue is likely specific to TED, supported by the fact that Harbour BioMed's (holder of '1401 license in China) review of blinded data across MG and ITP studies did not observe similar findings. However, it remains that a very real and meaningful increase in LDL levels (40-65%) was observed in the TED study and that it will take some time before sufficient analyses can be done to irrefutably answer the question whether this is TED specific. For now, we expect a significant overhang to remain given investors' probability of success, penetration, launch timing and strategic interest assumptions are all negatively impacted....

177. An analyst report on the Company by H.C. Wainwright & Co. dated February 17,

2021, stated, in pertinent part, as follows:

[M] an agement acknowledged that this effect may not simply be limited to TED and could be an undesirable side effect that Immunovant may have to manage commercially. If the lipid elevating effects are seen in MG or other indications, they could potentially be managed with statins, but would diminish the appeal of IMVT-1401 compared to argenx's (ARGX, Neutral) efgartigimod, that notably did not cause a cholesterol elevation upon treatment.

178. On June 1, 2021, the Company announced its financial and operational results for the fourth quarter 2021 ("4Q21") and for the full year ended March 31, 2021 ("FY21") in a press release (the "6/1/21 Press Release"), which it filed with the SEC on Form 8-K, and provided an update about the Company's investigation into the cholesterol issues announced on February 2, 2021. The 6/1/21 Press Release stated, in pertinent part, as follows:

In a program-wide review, the company observed increases in LDL in multiple studies that were consistent, dose-related, and appear to be driven by reductions in albumin levels. No relationship to levels of thyroid hormone was observed. The increases in LDL and reductions in albumin were reversible upon cessation of dosing, and no major adverse cardiovascular events have been reported to date.

* * *

As part of the company's data review, the Ph 2b TED study was unblinded and terminated prior to completion. While the trial showed clear biologic activity based on changes in IgG and pathologic autoantibodies, prematurely terminating the study resulted in inconclusive efficacy results . . . Efficacy data in this underpowered subset was more modest than the company had hoped and was not statistically significant on the primary endpoint.

- and LDL are tightly linked" and that "*[l]ipid elevations correlated tightly with albumin change and magnitude similar across indications*." The conclusions reported by Immunovant on June 1, 2021 are consistent with the information existing prior to and during the Class Period as alleged above concerning the effect of FcRn inhibition on serum albumin levels and, subsequently, on cholesterol levels.
 - 180. Following the Company's June 1, 2021 announcements, the price of Immunovant

stock fell from a closing price of \$15.16 per share on Friday, May 28, 2021, to a closing price of \$9.40 per share on June 1, 2021, a one day decline of \$5.76 per share, or 38%, on extremely heavy trading volume of 16.91 million shares.

181. An analyst report on the Company by Guggenheim dated June 1, 2021, stated, in pertinent part, as follows:

[T]he TED program, which was stopped after observed lipid changes, failed to produce robust efficacy in the Phase II...a path forward will require additional feedback from regulators/KOLs, and we think the potential is limited in this indication given the lack of robust efficacy and competition in the space... Downgrading to Neutral and removing our PT based on the limited potential for IMVT-1401 given the competitive landscape (ARGX's efgartigimod, HZNP's Tepezza) and the observed lipid safety issues, which are likely to be an issue for all proposed indications.

182. An analyst report on the Company by Credit Suisse dated June 1, 2021, stated, in pertinent part, as follows:

Increases in LDL Levels Across Programs Put a Dent on Competitive Profile. IMVT confirmed that increased LDL levels previously observed from the TED Ph2b (ASCENDGO-2) trial were in fact consistent and dose-related across multiple studies (believed to be driven by reductions in albumin), and not correlated with thyroid hormone levels. While IgG reductions in the ASCEND-GO-2 trial were robust at higher doses (340mg and 680mg), the increases in LDL and lower than expected efficacy (41 of planned 77 patients reached 12w endpoint) may confine IMVT-1401 to lower doses (255mg)—limiting the appeal in TED . . . While ultimately the LDL levels might be manageable, we think IMVT-1401 may struggle to differentiate favorably to other FcRn agents that have minimal impact to albumin levels. As a result, we lower to TP to \$12 to reflect the lower probability-of-success (PoS) in TED and the heightened uncertainty across other programs (lower PoS/peak sales).

183. The price of Immunovant common stock closed at \$6.99 on February 1, 2022.

Immunovant's Emphasis on a New Drug Called IMVT-1402 Illustrates the Importance of the Elevations in Cholesterol Caused by IMVT-1401

184. The elevations in cholesterol reported in the ASCEND GO-2 Phase 2b trial had a substantial impact on Immunovant's business and strategy. Indeed, even though Immunovant could potentially sell IMVT-1401 to patients if it ultimately obtains FDA approval, the potential size of the

market is much smaller due to the elevations in cholesterol. The reduction in the size of the potential market for IMVT-1401 is explained in the following excerpt from an article titled "Uncertainty Looms Over Immunovant's Future As Batoclimab Faces Dim Prospects" on Seeking Alpha dated March 6, 2023 (the "March 6 Seeking Alpha article"):

Suppose you are a patient with a chronic, debilitating disorder, and your doctor presents you with two drugs, X and Y. She explains that these drugs have almost identical mechanisms of action, cost the same, and are thought to be equally effective. However, she also informs you that drug X is known to cause an increase in LDL-C, which is a key risk factor for cardiovascular disease. If you choose drug X, you will need to take an additional medication, which may worsen your symptoms, to reduce LDL-C. Given this information, which drug would you prefer to take?

Furthermore, consider the potential regulatory and indication implications of using batoclimab in patients with MG. Would these patients need to undergo frequent LDL-C monitoring through a REMS program, and is it necessary to prescribe a statin along with batoclimab? Additionally, is it safe for a practitioner to prescribe batoclimab to a MG patient who already has cardiovascular risk factors?

- 185. Instead of focusing exclusively on IMVT-1401, Immunovant sought to develop a new drug named IMVT-1402. As reflected in the Company's statements, Immunovant's goal was to create a drug which did not elevate cholesterol.
- 186. On March 30, 2022, the Company announced a virtual R&D event in a press release, which it filed with the SEC on Form 8-K along with a corresponding PowerPoint presentation (the "March 30 Presentation"). The March 30 Presentation included information on cholesterol management presented by Immunovant's newly appointed Chief Medical Officer, Bill Macias, and Michael Davidson, Professor and Director of the Lipid Clinic at the University of Chicago Pritzker School of Medicine.
- 187. In the March 30 Presentation, the Company detailed the causes of cardiovascular disease and emphasized how "[c]ontrol of lipid levels is one of the most effective strategies for [cardiovascular disease] prevention." The March 30 Presentation stated, "[i]n medical practice, there

are a number of therapies that increase LDL-C[.] and that "LDL changes correlated with on target changes in albumin[.]"

- 188. On September 28, 2022, Immunovant issued a press release and presentation (the "September 2022 Presentation") announcing IMVT-1402, a Next Generation Anti-FcRn (the "9/28/22 Press Release"), which it filed with the SEC on Form 8-K. The 9/28/22 Press Release quoted Defendant Salzmann as stating: "As with batoclimab, IMVT-1402 may offer deep, potentially best-in-class IgG reduction formulated for the same simple subcutaneous route of administration delivered in a matter of seconds. Additionally, *IMVT-1402 has been observed to have minimal or no impact on levels of albumin and LDL in animal studies*." The Company emphasized how IMVT-1402 was similar to IMVT-1401 except for its impact on albumin, stating "[a]nimal studies have demonstrated IMVT-1402 may have deep, potentially best-in-class IgG lowering, similar to batoclimab, *and yet may have minimal impact on albumin and LDL*" and that "[a]nimal studies suggest deep dose-dependent IgG lowering similar to batoclimab[.]"
- 189. The September 2022 Presentation also provided investors with monkey study results comparing the similarities between IMVT-1402 and batoclimab and emphasized how "Cynomolgus monkeys observed to be reliable pharmacodynamic proxy for anti-FcRn mediated impacts on IgG[.]" Further, the September 2022 Presentation provided investors with side-by-side comparisons of batoclimab and IMVT-1402 to show how the latter was designed to minimize interference with the albumin binding site while ultimately retaining similarities to batoclimab.
- 190. On October 4, 2022, Immunovant issued a press release announcing the pricing of a \$75.0 million public offering of common stock (the "10/4/22 Press Release"), which it filed with the SEC on Form 8-K. The 10/4/22 Press Release explained the offering was aimed at IMVT-1402's development and stated, in pertinent part, "[t]he company intends to use the net proceeds from this

offering, together with its existing cash, to accelerate the development of IMVT-1402, including the funding of a proposed pivotal trial."

- 191. In a Corporate Presentation about IMVT-1402 titled "Rethinking possibilities in autoimmune diseases" (the "November 2022 Presentation"), Immunovant emphasized that "[a]nimal studies suggest deep dose-dependent IgG lowering similar to batoclimab" and explained that "[a]nimal studies support the potential for a favorable analyte profile with no or minimal effect on albumin and LDL[.]"
- 192. Immunovant repeatedly focused on animal studies, albumin levels, and lipid profiles when discussing its development of IMVT-1402 in comparison to IMVT-1401. On November 4, 2022, the Company filed its quarterly report on Form 10-Q with the SEC for 2Q22 (the "2Q22 Form 10-Q"). The 2Q22 Form 10-Q revealed details about animal studies previously conducted for batoclimab and stated, in pertinent part, as follows:

Our second product candidate, IMVT-1402, has been observed in animal studies to reduce IgG antibody levels with minimal or no impact on levels of albumin and low-density lipoprotein ("LDL") at doses well above the anticipated human effective dose; similar doses of batoclimab in animals were clearly associated with declines in albumin.

- 193. The 2Q22 Form 10-Q further warned about the potential risk for decreased albumin and increased cholesterol in IMVT-1402, stating, "[IMVT-1402] has not affected lipid or albumin levels in current completed nonclinical studies, it may do so in human clinical trials."
- 194. Even though Immunovant has been developing IMVT-1402, it will be years before the Company will be able to generate sales from that drug. According to the March 6 Seeking Alpha article, "[a]ssuming that IMVT-1402 is both effective and safe, it could take at least seven years before it becomes available in the market."

COUNT I

Violations of Section 11 of the Securities Act Against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants

- 195. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 196. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, and is asserted against Immunovant, the Underwriter Defendants, and the Securities Act Individual Defendants. Plaintiff does not claim for purposes of this Count that Defendants committed intentional or reckless misconduct or acted with scienter or fraudulent intent.
- 197. The Registration Statement for the September 2020 Offering was inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein.
- 198. Immunovant is the registrant for the September 2020 Offering. As issuer of the shares, Immunovant is strictly liable for the materially inaccurate statements contained in the Registration Statement and the Prospectus and the failure of the Registration Statement and Prospectus to be complete and accurate.
- 199. The Securities Act Individual Defendants each signed the Registration Statement either personally or through an Attorney-in-Fact and/or caused its issuance. The Securities Act Individual Defendants each had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statement. They had a duty to ensure that such statements were true and accurate, that there were no omissions of material fact that would make the statements misleading and that the documents contained all facts required to be stated therein. In the exercise of reasonable care, the Securities Act Individual Defendants should

have known of the material misstatements and omissions contained in the Registration Statement and also should have known of the omissions of material fact that were necessary to make the statements made therein not misleading. As such, the Securities Act Individual Defendants are liable to Plaintiff and the Class.

- 200. The Underwriter Defendants were each underwriters, as that term is used in Section 11(a)(5) of the Securities Act, with respect to the September 2020 Offering and the Company's securities were sold through the Registration Statement. The Underwriter Defendants were required to investigate with due diligence the representations contained therein to confirm that they did not contain materially misleading statements or omit material facts. None of the Underwriter Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements described herein, which were contained in the Registration Statement and Prospectus, were true, were without omission of any material facts, and/or were not misleading.
- 201. By reasons of the conduct herein alleged, each Defendant violated Section 11 of the Securities Act.
- 202. Plaintiff and putative Class members acquired Immunovant common stock in the September 2020 Offering, and in reliance on the Registration Statement and without knowledge of the untruths and/or omissions alleged herein. Plaintiff and the Class sustained damages when the price of IMVT securities declined substantially subsequent to and due to Defendants' violations.

COUNT II

Violations of Section 12(a)(2) of the Securities Act Against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants

- 203. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 204. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l, on behalf of Plaintiff and the Class, against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants (the "Count II Defendants"). Plaintiff does not claim for purposes of this Count that Defendants committed intentional or reckless misconduct or acted with scienter or fraudulent intent.
- 205. The Count II Defendants were sellers and offerors and/or solicitors of purchasers of the securities offered pursuant to the September 2020 Offering Prospectus. The Count II Defendants issued, caused to be issued, and/or signed the Registration Statement in connection with the September 2020 Offering. The Registration Statement contained a Prospectus which was used to induce investors, such as Plaintiff and the other members of the Class, to purchase Immunovant securities.
- 206. The September 2020 Offering Prospectus contained untrue statements of material fact, omitted to state other facts necessary to make the statements made not misleading, and omitted material facts required to be stated therein. The Securities Act Individual Defendants' actions of solicitation included participating in the preparation of the false and misleading Prospectus and in road shows to promote the September 2020 Offering. Immunovant and the Underwriter Defendants, acting through their employees, agents, and others, solicited such purchases for their personal financial gain through the preparation and dissemination of the Prospectus.
 - 207. The Underwriter Defendants participated in the preparation and dissemination of the

false and misleading Prospectus for their own financial benefit. But for their participation in the September 2020 Offering, including their solicitation as set forth herein, that offering could not and would not have been accomplished. Specifically, the Underwriter Defendants:

- (a) made the decision to conduct the September 2020 Offering and do it at the price set forth in the offering documents. The Underwriter Defendants drafted, revised and/or approved the Prospectus. The Prospectus was calculated to create interest in Immunovant securities and was widely distributed by or on behalf of these Defendants for that purpose;
 - (b) finalized the Prospectus and caused it to become effective; and
- (c) conceived and planned the September 2020 Offering and orchestrated all activities necessary to affect the sale of these securities to the investing public, by issuing securities, promoting the securities and supervising their distribution and ultimate sale to the investing public.
- 208. As set forth more specifically above, the Prospectus contained untrue statements of material fact and omitted to state material facts necessary in order to make the statements, in light of circumstances in which they were made, not misleading.
- 209. Plaintiff and the other Class members did not know, nor could they have known, of the untruths or omissions contained in the Prospectus.
- 210. The Count II Defendants were obligated to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission of material fact required to be stated in order to make the statements contained therein not misleading. None of the Count II Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Prospectus were accurate and complete in all material respects. Had they done so, these Defendants would have known of the material misstatements and omissions alleged herein.

211. By reason of the conduct alleged herein, the Count II Defendants violated Section 12(a)(2) of the Securities Act. Accordingly, Plaintiff and members of the Class who hold Immunovant common stock purchased in the Offering have the right to rescind and recover the consideration paid for their Immunovant common stock and hereby elect to rescind and tender their Immunovant common stock to the Defendants sued herein. Plaintiff and Class members who have sold their Immunovant common stock are entitled to rescissory damages.

COUNT III

Violations of Section 15 of the Securities Act Against the Securities Act Individual Defendants and Roivant

- 212. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 213. This Count is brought pursuant to Section 15 of the Securities Act against the Securities Act Individual Defendants and Roivant. Plaintiff does not claim for purposes of this Count that Defendants committed intentional or reckless misconduct or acted with scienter or fraudulent intent.
- 214. Each of the Securities Act Individual Defendants and Roivant acted as controlling persons of Immunovant within the meaning of Section 15 of the Securities Act by virtue of their position as a director and/or senior officer of Immunovant and/or equity interest in and control of the Company. By reason of their senior management positions, directorships at the Company, or stock ownership, as alleged above, the Securities Act Individual Defendants and Roivant, individually and acting pursuant to a common plan, had the power to influence and exercised the same to cause Immunovant to engage in the conduct complained of herein. By reason of such conduct, the Securities Act Individual Defendants and Roivant are liable pursuant to Section 15 of the Securities Act.

215. Each of the Securities Act Individual Defendants and Roivant was a culpable participant in the violations of Sections 11 and 12(a)(2) of the Securities Act alleged in Counts I and II above, based on their having signed the Registration Statement and having otherwise participated in the process which allowed the September 2020 Offering to be successfully completed.

ADDITIONAL ALLEGATIONS IN SUPPORT OF CLAIMS UNDER THE EXCHANGE ACT

216. For purposes of the allegations under the Exchange Act set forth herein, the Exchange Act Individual Defendants refers to Defendants Salzmann and Wong and together with Immunovant and Roivant, the "Defendants."

The Fraudulent Scheme: Immunovant Delayed the Monitoring and Assessment of Cholesterol Levels and the Disclosure of the Potential Risk of Cholesterol Elevations to Provide Time to Raise Hundreds of Millions of Dollars in Stock Offerings and to Obtain 20 Million Earnout Shares

- 217. Numerous facts existing by the start of the Class Period show that Defendants knew, or recklessly disregarded, that elevated LDL and cholesterol levels were potential risks of IMVT-1401. Instead of disclosing this potential risk to investors, Defendants engaged in a fraudulent scheme and hid that risk from investors to enable the Merger with HSAC to go through, for Defendants to obtain 20 million Earnout shares valued at \$600 million, and for Immunovant and others to sell hundreds of millions of dollars in Immunovant shares in several follow-on stock offerings.
- 218. Even though Defendants apparently recognized they would need to assess the impact of IMVT-1401 on cholesterol eventually, they delayed having to address that issue by choosing not to assess cholesterol in early clinical trials of IMVT-1401. Therefore, even though they assessed cholesterol in the ASCEND GO-2 Phase 2b trial, the results from that trial were not scheduled for release until the first quarter of 2021, more than a year after the Merger. And elevations in cholesterol were merely a *potential* risk as opposed to something which was guaranteed to occur so

there was a chance cholesterol would not be elevated in the ASCEND GO-2 Phase 2b trial. In that unlikely event, Defendants may have been able to move forward with clinical trials which were not disrupted by revelations of elevations in cholesterol. As alleged herein, however, the ASCEND GO-2 Phase 2b trial did reveal elevations in cholesterol. Nevertheless, Defendants still profited from the fraud alleged herein.

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

- 219. Throughout the Class Period, Defendants made materially false and misleading statements and omitted material information about Immunovant, IMVT-1401, and the safety and potential risks of IMVT-1401. Defendants misrepresented and failed to disclose the following adverse facts, which were known to Defendants or recklessly disregarded by them:
 - (a) IMVT-1401 was less safe than represented by Defendants;
- (b) There was a potential risk and anticipated risk MVT-1401 would substantially increase LDL and total cholesterol levels because, among other reasons:
- (i) Immunovant's animal studies for IMVT-1401 revealed a substantial increase in cholesterol for animals which received IMVT-1401;
- (ii) IMVT-1401 was in a class of drug which lowered serum albumin levels, and medical journals and studies reported that low serum albumin levels increase LDL and total cholesterol levels;
- (iii) Thyroid conditions which were indications for IMVT-1401, such as Grave's Ophthalmopathy and myasthenia gravis, are known to reduce cholesterol, so if IMVT-1401 is successful in treating the underlying thyroid condition, it should be expected that cholesterol would increase;
 - (iv) Other companies researching the same class of drug apparently

recognized this risk because they tested cholesterol levels;

- (v) Immunovant monitored cholesterol in the ASCEND GO-2 Phase 2b trial because it was a potential risk;
- (c) Immunovant's statements about IMVT-1401's clinical trials, including about safety results, failed to incorporate an assessment of the potential risk of elevated cholesterol levels;
- (d) Immunovant failed to follow FDA regulations and Good Clinical Practices in connection with IMVT-1401 because it failed to perform ongoing surveillance of the adverse events and suspected adverse reactions of elevated LDL and total cholesterol levels;
- (e) The undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or disrupt IMVT-1401's prospects for commercial viability and profitability; and
- (f) Immunovant's business, operations and financial condition was not as represented.
- 220. Specifically, Defendants misrepresented and omitted material information about: (i) IMVT-1401's completed clinical trials and trial results; (ii) the potential negative impact of albumin reductions caused by IMVT-1401 and the availability of studies and reports indicating albumin reductions elevate cholesterol and are linked to heart disease; (iii) Immunovant's failure to comply with Good Clinical Practices; and (iv) IMVT-1401's animal studies.
- 221. The Class Period starts on October 2, 2019. On that date, Immunovant and HSAC issued a press release (the "10/2/19 Press Release") titled "Immunovant to Merge with Health Sciences Acquisitions Corporation, Creating New Publicly Listed FcRn-Focused Company," announcing the Merger between HSAC and Legacy Immunovant. The 10/2/19 Press Release discussed the terms of the merger, highlighted that a Phase 1 study of IMVT-1401 had "delivered a

mean IgG reduction of nearly 80%" and advised there were two ongoing Phase 2a trials with top-line data expected during the first half of 2020, stating, in pertinent part, as follows:

- Immunovant is developing IMVT-1401, a fully human antibody to FcRn that delivered a mean IgG reduction of nearly 80% in a Phase 1 study of healthy volunteers receiving 4 weekly 680 mg subcutaneous injections
- Top-line data from ongoing *Phase 2a trial in Graves' ophthalmopathy expected* by Q1 2020
- Top-line data from ongoing *Phase 2a trial in myasthenia gravis expected by Q2 2020*
- 222. Defendants Wong and Salzmann both made very positive statements about IMVT-1401 in the 10/2/19 Press Release, stating in pertinent part, as follows:

"We are thrilled to have the opportunity to partner with the team at Immunovant. We believe *IMVT-1401 is a uniquely compelling asset* within the FcRn drug class, which we expect *will become a cornerstone therapy* for treating many auto-antibody driven diseases," *said Roderick T. Wong, M.D.*, President, Chief Executive Officer and Chairman of HSAC and Managing Partner and Chief Investment Officer of RTW Investments.

* * *

"I am proud of the many milestones delivered by the Immunovant team this year, including completion of a comprehensive Phase 1 program demonstrating robust IgG reductions with simple subcutaneous injections and initiation of a broad Phase 2 program with both first-in-class and best-in-class potential in multiple diseases with high unmet patient need. We believe the potency of IMVT-1401 and the ability to administer IMVT-1401 as a simple subcutaneous injection represent important potentially differentiating features of this product candidate. Today's financing transaction will allow us to continue to pursue our vision of enabling normal lives for patients with autoimmune diseases," said Pete Salzmann, M.D., Chief Executive Officer of Immunovant.

223. The statements referenced above in ¶221-222 were materially false and misleading when made because they discussed the positive aspects of IMVT-1401 without disclosing the potential risk that IMVT-1401 elevates cholesterol. Defendant Wong's statement referenced in ¶222, "[w]e believe IMVT-1401 is a uniquely compelling asset . . . which we expect will become a cornerstone therapy" was materially false and misleading because it was a potential risk IMVT-1401

would elevate cholesterol and that IMVT-1401 could not be described as uniquely compelling or a cornerstone therapy until after IMVT-1401's impact on cholesterol is assessed. Defendant Salzmann's statement about a "comprehensive Phase 1 program" and "broad Phase 2 program with both "first-in-class and best-in-class potential" were materially false and misleading because early clinical trials did not assess the key potential risk of elevated cholesterol.

- 224. On or about October 2, 2019, Immunovant filed the 10/2/19 Press Release with the SEC on Form 8-K along with an Investor Presentation dated October 2, 2019 (the "Merger Presentation"). The Merger Presentation provided details about the terms of the Merger between Legacy Immunovant and HSAC, including that "near-term value drivers" for Immunovant stock were "[f]our anticipated data readouts over the next 20 months." Additionally, the Merger Presentation misrepresented and omitted material facts about IMVT-1401 and the IMVT-1401 clinical trials.
- 225. The Merger Presentation highlighted the opportunities for IMVT-1401, discussed the success of the IMVT-1401 Phase 1 trial due to "meaningful IgG reductions" and described IMVT-1401 as "well-tolerated." The Merger Presentation contained a slide titled "IMVT-1401: Program Highlights," which stated as follows:

IMVT-1401: Program Highlights

IMVT-1401: A novel, fully human monoclonal antibody inhibiting FcRn

 Early evidence suggests that anti-FcRn agents could transform the treatment of autoimmune diseases mediated by pathogenic IgG antibodies

In Phase 1, IMVT-1401 generated compelling pharmacodynamic activity

- Clinically meaningful IgG reductions observed (78% IgG reduction at 680mg dose level)
- No difference observed between intravenous and subcutaneous formulations at equivalent doses

IMVT-1401 has been well tolerated to date

- · No headaches reported in the highest dose multiple dose cohort tested
- · No treatment-related serious adverse events (SAEs) or dose limiting toxicities reported
- · No confirmed cases of anti-drug antibodies in any subject in multiple dose cohorts

IMVT-1401 was designed from inception for subcutaneous (SC) injection

- · Requirement during development process
- · Phase 1 data suggest every other week or less frequent dosing achievable for chronic use



- 226. The statements referenced above in ¶224-225 were materially false and misleading when made because they discussed the positive aspects of IMVT-1401 without disclosing a key potential risk that IMVT-1401 could elevate cholesterol levels. Additionally, the statements that "IMVT-1401 has been well tolerated to date" and that there were "no treatment-related serious adverse events (SAEs)" were materially false and misleading when made because there was a potential risk IMVT-1401 elevated cholesterol. Additionally, Defendants lacked a reasonable basis to make statements about IMVT-1401 being "well tolerated" and with no "serious adverse events" because early clinical trials did not assess the potential risk of elevated cholesterol. A reasonable investor would have expected that those statements were made after an assessment of all key potential risks when that was not the case.
- 227. The Merger Presentation contained a slide titled "Generally well-tolerated in Phase 1 study" which stated the following:

Generally well-tolerated in Phase 1 study

Preliminary results from Phase 1 SAD/MAD cohorts

- 99 subjects dosed to date through SAD and MAD portions of Phase 1
 - IMVT-1401: 77 subjects
 - Placebo: 22 subjects
- · Most common AEs were mild erythema and swelling at injection site
 - Injection site reactions were not dose or frequency related
 - Occurred at similar incidence for drug and placebo treated subjects
- · No headaches observed in 680mg SC MAD cohort
- · Albumin changes:
 - Dose-dependent, reversible, and asymptomatic albumin reductions observed
 - At day 28, mean albumin levels were 37.5 g/L in the 340 mg cohort, and 32.4 g/L in 680mg cohort (normal range 36-51 g/L)
- 2 SAEs observed in two separate SAD cohorts, both ruled unrelated to treatment by study investigator (cancer, appendicitis)
- Treatment-emergent ADA confirmed in 8% of IMVT-1401-treated subjects and 6% of placebo-treated subjects
 - No subject in MAD cohorts has developed a confirmed ADA response to IMVT-1401



- 228. The statements referenced above in ¶227 were materially false and misleading when made because they failed to disclose a key potential risk that IMVT-1401 could elevate cholesterol levels. Additionally, the statements, "Generally well tolerated" and "most common AEs" were materially false and misleading because Defendants lacked a reasonable basis to make those statements because the clinical trial did not assess cholesterol. A reasonable investor would have expected those statements were made after an assessment of all key potential risks when that was not the case. Furthermore, the statements about albumin reductions in a slide about IMVT-1401 being "well-tolerated" created the duty for Defendants to disclose that serum albumin reductions may lead to cholesterol elevations.
- 229. The Merger Presentation contained several slides about why IMVT-1401 is a promising treatment for Myasthenia Gravis, including a slide titled "Unmet need persists despite availability of treatment options," stating as follows:

Unmet need persists despite availability of treatment options

Current treatment paradigm¹

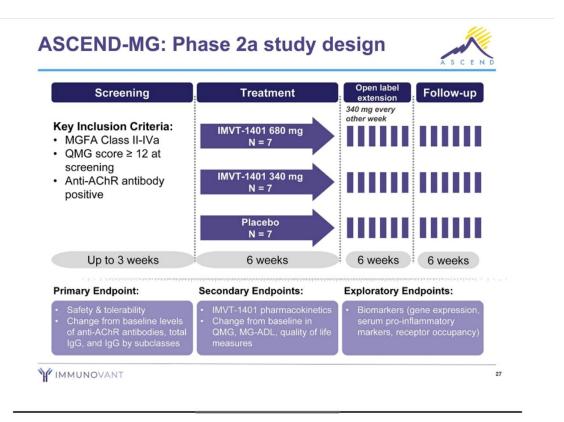
1 st Line	2 nd Line	3 rd Line	4 th Line
Acetylcholinesterase inhibitors Corticosteroids	Immunosuppressive agents Thymectomy	IVIg Plasma exchange Immunoadsorption Rituximab (off-label)	Eculizumab

Unmet need

- ~10% of MG patients refractory to current treatments, while 80% fail to achieve complete stable remission¹
- · Existing therapies associated with significant side effects
 - Early line agents can lead to disease exacerbation and do not always prevent disease progression
 - Treatment for more advanced disease often requires invasive and burdensome infusions
- Patients with anti-MuSK antibodies more likely to become refractory¹
 - ~50% of the refractory MG population, despite comprising <10% of the overall MG population
 - Newest treatment option, eculizumab, only indicated for anti-AChR positive patients



- 230. The statements referenced above in ¶229 were materially false and misleading when made because they discussed the potential opportunity for IMVT-1401 and the negative aspects of alternatives but failed to disclose a potential risk of IMVT-1401 is elevated cholesterol. The statement "existing therapies associated with significant side effects" was materially misleading because Defendants failed to disclose elevations in cholesterol was key potential side effect of IMVT-1401.
- 231. The Merger Presentation contained a slide titled "ASCEND-MG: Phase 2a study design," stating as follows:



- 232. The statements referenced above in ¶231 were materially false and misleading when made because they failed to disclose elevated cholesterol was a key potential risk of IMVT-1401 and that the trial reflected on that page did not monitor or assess that key potential risk. The statement that "safety & tolerability" were "Primary Endpoints" was materially false and misleading because that clinical trial failed to assess a key potential safety and tolerability issue of elevated cholesterol.
- 233. The Merger Presentation contained several slides about why IMVT-1401 is a promising treatment for Graves' Ophthalmopathy, including a slide titled "Limited treatment options for GO," stating as follows:

Limited treatment options for GO

Current treatment paradigm¹

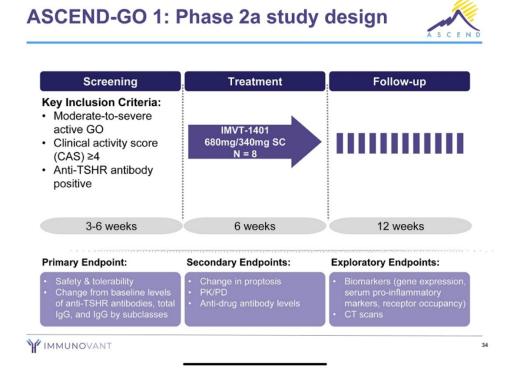
1 st Line	2 nd Line	3 rd Line	Inactive disease	
Corticosteroids	Orbital radiotherapy Immunosuppressive agents		Orbital surgery	

Unmet need

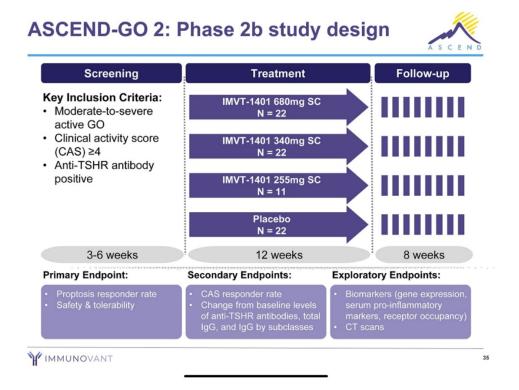
- · Currently no FDA-approved therapies for GO
- · Corticosteroids are not effective in all patients, and approximately one-third of patients will relapse
- Sight-threatening disease may occur in 3-5% of patients with Graves' disease²
 - Medical emergency requiring immediate hospitalization and evaluation for surgery²
- Up to 20% of GO patients require surgical invervention²



- 234. The statements referenced above in ¶233 were materially false and misleading when made because they discussed the market for treatments for GO and the negative effects of other options but fails to disclose a key potential risk of elevated cholesterol.
- 235. The Merger Presentation contained several slides concerning the ASCEND-GO Phase 2 trials, including a slide titled "ASCEND-GO 1: Phase 2a study design" stating as follows:



- 236. The statements referenced above in ¶235 were materially false and misleading when made because they failed to disclose elevated cholesterol was a key potential risk of IMVT-1401 and that the trial reflected on that page did not monitor or assess that key potential risk. The statement that "safety & tolerability" were "Primary Endpoints" was materially false and misleading because that clinical trial failed to assess a key potential safety and tolerability issue of elevated cholesterol.
- 237. The Merger Presentation contained several slides concerning the ASCEND-GO Phase 2 trials, including a slide titled "ASCEND-GO 2: Phase 2b study design" stating as follows:



238. The statements referenced above in ¶237 were materially false and misleading when made because they failed to disclose elevated cholesterol was a key potential risk of IMVT-1401 and that the ASCEND GO-2 Phase 2b trial, unlike the other clinical trial, was monitoring and assessing cholesterol. As a result, there was an undisclosed risk that trial could be disrupted if that trial identified elevations in cholesterol.

Misstatements and Omissions Regarding Immunovant's Compliance with Good Clinical Practices

- 239. Defendants represented during the Class Period that the IMVT-1401 clinical trials complied with Good Clinical Practices and FDA rules and procedures even though Defendants knew, or recklessly disregarded, that those statements were not accurate.
- 240. On or about November 27, 2019, HSAC filed a proxy statement with the SEC in support of the Merger (the "11/27/19 Proxy"), which was signed by Defendant Wong. The Share Exchange Agreement for the Merger, which was signed by Defendant Wong, on behalf of HSAC

and the RTW entities, Defendant Roivant, and Legacy Immunovant, and annexed to the 11/27/19 Proxy, stated, in pertinent part, as follows:

- 4.27 Preclinical Development and Clinical Trials. The studies, tests, preclinical development and clinical trials, if any, conducted by or on behalf of the Company are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company and all applicable laws and regulations, including the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. parts 50, 54, 56, 58, 312, and 812. The descriptions of, protocols for, and data and other results of, the studies, tests, development and trials conducted by or on behalf of the Company that have been furnished or made available to the Purchaser or as provided in the Proxy Statement are accurate and complete in all material respects (other than to the extent certain portions thereof were redacted by the Company). The Company is not aware of any studies, tests, development or trials the results of which reasonably call into question the results of the studies, tests, development and trials conducted by or on behalf of the Company[.]
- 241. The statements referenced above in ¶240 were materially false and misleading when made because the early clinical trials for IMVT-1401 were not monitoring or assessing a key risk of elevated cholesterol. Additionally, the statement that the clinical trials "are being conducted…in accordance with…accepted professional and scientific standards" was materially false and misleading because Immunovant and IMVT-1401's early clinical trials failed to adhere to good clinical practices, as alleged above.

Defendants Continued Making Materially False and Misleading Statements and Omitted Material Information

242. Throughout the rest of the Class Period, Defendants repeated many of the materially false and misleading statements set forth above and failed to correct any of their prior misstatements or omissions. In press releases, SEC filings, and during conference calls and at conferences, Defendants continued to highlight the positive aspects of IMVT-1401 but failed to publicly disclose there was a meaningful potential risk IMVT-1401 could elevate LDL and cholesterol levels and lead to coronary disease and that the results from early clinical trials of IMVT-1401 did not incorporate

assessments of the key risk of elevations in cholesterol. Defendants continued to minimize the negative impact of albumin reductions caused by IMVT-1401 and misrepresented the existence of numerous articles and studies discussing the impact of albumin reductions on cholesterol. Furthermore, Defendants misrepresented and omitted facts concerning IMVT-1401's pre-clinical animal studies, including failing to disclose Immunovant's animal studies revealed substantial elevations in cholesterol for monkeys which took IMVT-1401.

243. As time progressed Defendants reported the results of completed clinical trials, failed to disclose clinical trials did not assess the key potential risk of elevated cholesterol, and made incomplete and misleading statements concerning the safety, tolerability and adverse events (AEs) of IMVT-1401.

Additional Misstatements and Omissions Regarding IMVT-1401 Clinical Trials

- 244. On October 11, 2019, Health Sciences Acquisitions Corporation and Immunovant Sciences Ltd. hosted a conference call regarding the merger (the "10/11/19 Merger Call"). Defendant Wong stated, in pertinent part, "[w]e've been impressed by [IMVT-1401's]...robust reduction in IgG levels in comprehensive Phase I program."
- 245. Defendant Wong's statement above in ¶244, "[w]e've been impressed by its…robust reduction in IgG levels in comprehensive Phase I program" was materially false and misleading when made because Defendant Wong knew, or recklessly disregarded, that the Phase I program was not "comprehensive" because it did not assess the important potential risk of elevated cholesterol.
- 246. On the 10/11/19 Merger Call, Defendant Salzmann stated, in pertinent part, as follows:

To these ends, I'm proud of the many milestones delivered by the Immunovant team this year, including *completion of a comprehensive Phase 1 program demonstrating robust IgG reductions of 78%* with simple weekly subcutaneous injections of 680 milligrams....We've also initiated a broad Phase 2 program with both first-in-class and best-in-class potential in multiple diseases with high unmet patient need.

Importantly, IMVT-1401 was also generally well tolerated in this good-sized Phase 1 trial.

247. Defendant Salzmann's statements referenced in ¶246 above were materially false and misleading when made because he highlighted the positive results of the Phase 1 program, described it as "comprehensive" and stated IMVT-1401 was "well-tolerated" even though he knew or recklessly disregarded that those results did not include an assessment of a key potential risk of elevated cholesterol. Additionally, Defendant Salzmann lacked a reasonable basis to represent that IMVT-1401 was "well-tolerated" because he knew, or recklessly disregarded that he was not in a full position to know whether it was well tolerated because Immunovant did not monitor cholesterol levels. A reasonable investor would have expected Immunovant's clinical trials to have monitored and assessed all key potential risks and that Defendant Salzmann's statements included assessments of those risks.

248. On January 17, 2020, Immunovant filed its Form S-1 Registration Statement with the SEC (the "1/17/20 Registration Statement"), which was signed by, among others, Defendants Salzmann, Torti, Fromkin, Hughes, Migausky, and Pande. The 1/17/20 Registration Statement stated, in pertinent part, as follows:

ASCEND-MG Trial

In August 2019, we initiated dosing in a randomized, blinded, placebo-controlled Phase 2a clinical trial of IMVT-1401 for the treatment of MG. *The ASCEND-MG trial assesses safety and efficacy of IMVT-1401* in an anticipated 21 patients with MG symptoms, as defined by MGFA Class II through IVa, and QMG scores greater than or equal to 12 . . . *The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401* and identification of optimal dosing for Phase 3 administration through measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG . . . We anticipate reporting top-line results from this trial in the first half of 2020.

* * *

ASCEND-GO 1 Trial

In May 2019, we initiated dosing in our ASCEND-GO 1 trial, an open label single-arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with GO . . . The primary endpoints of this trial will be safety and tolerability of IMVT-1401 over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses...We anticipate reporting initial results from this trial in the first quarter of 2020.

* * *

ASCEND-GO 2 Trial

In October 2019, we initiated dosing in our ASCEND-GO 2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 patients with moderate-to-severe active GO with confirmed autoantibodies to TSHR. The ASCEND-GO-2 trial explores the potential of IMVT-1401 to improve proptosis, and assesses the safety and tolerability of IMVT-1401 in this population . . . The primary endpoints of this trial are the proptosis responder rate measured at week 13, defined as the percentage of patients with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, and safety and tolerability . . . We anticipate reporting initial results from this trial in early 2021.

249. The statements referenced above in ¶248 were materially false and misleading when made because they made positive statements about the IMVT-1401 clinical trial program and made it appear as if things were progressing smoothly but failed to disclose that elevations cholesterol was a key potential risk of IMVT-1401. The statements "[t]he ASCEND MG trial assesses safety and efficacy of IMVT-1401" and that the "primary endpoints" of the ASCEND-GO-1 Trial were "safety and tolerability" were materially false and misleading when made because neither of those trials assessed safety or tolerability issues with respect to cholesterol. Additionally, the description of the ASCEND GO-2 Phase 2b trial as "assessing the safety and tolerability" used the exact same language as the other two trials even though the trials were very different because the ASCEND GO-2 Phase 2b trial was monitoring and assessing cholesterol when the others were not. There is no indication from Defendants' statements that the ASCEND GO-2 Phase 2b trial was monitoring a potential risk for the first time which could result in a delay or disruption of the clinical trial program

and schedule.

250. The 1/17/20 Registration Statement also stated, in pertinent part, as follows:

Safety Data

In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo.... To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. There have been no treatment-related serious AEs reported.

- 251. The statements referenced above in ¶250 were materially false and misleading when made because they highlighted positive information about the safety and tolerability of IMVT-1401 but failed to disclose there was a potential risk IMVT-1401 would elevate cholesterol and that the referenced results did not include assessments of the key anticipated risk of elevated cholesterol levels. Statements such as "IMVT-1401 has been observed to be well-tolerated" and there "have been no treatment-related serious AEs reported" were materially false and misleading when made because elevated cholesterol was a potential risk and that trial did not assess that risk. A reasonable investor would have expected those statements to be made only after an assessment of all key potential risks. Additionally, Defendants lacked a reasonable basis to represent there had been "no treatment-related serious AEs" because patients may have experienced elevated cholesterol.
- 252. On March 30, 2020, the Company announced clinical results from a Phase 2a proof-of-concept study of IMVT-1401 in a press release (the "3/30/20 Press Release"), which it filed with the SEC on Form 8-K. Defendant Salzmann was quoted in the 3/30/20 Press Release and stated, in pertinent part, as follows:

We are very excited by the initial results of this trial...[t]hese results provide an early proof-of-concept of the potential for IMVT-1401 to ultimately become a safe and effective treatment for patients suffering from Thyroid Eye Disease . . . [w]e look forward to reporting the study's full results, including detailed lab observations and 12 weeks of follow up data, at an upcoming medical meeting.

- 253. The statements referenced above in ¶252 were materially false and misleading when made because Defendant Salzmann knew, or recklessly disregarded, that elevated cholesterol was a potential risk of IMVT-1401 and that clinical trial did not assess that risk. Defendant Salzmann did not have a reasonable basis to state that the results provide an "early proof-of-concept" because that clinical trial had not assessed cholesterol. Additionally, contrary to Defendant Salzmann's statement, he did not have "detailed lab observations" because the clinical trial did not test cholesterol.
- 254. On March 30, 2020, the Company held a conference call with analysts and investors (the "3/30/20 Conf Call") to discuss information set forth in the 3/30/20 Press Release. During the 3/30/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

I would like to start off by expressing how thrilled we are about the *positive clinical* results we are announcing today in thyroid eye disease. As the only subcutaneous therapy in clinical development for thyroid eye disease, we believe IMVT-1401 has the potential to be life-changing for patients, and we couldn't be happier with the outcome of this small proof-of-concept trial.

ASCEND GO-1 is the first trial of an anti-FcRn in thyroid eye disease. We had 2 major objectives for this trial: first, the study was designed to test the pharmacodynamic response to a loading dose regimen; second, *the study was designed to examine the initial safety and efficacy of IMVT-1401* in thyroid eye disease.

We are also pleased to report that the safety and tolerability profile we observed in ASCEND GO-1 was in line with our expectations from our Phase 1 study in 99 healthy volunteers. We saw no serious adverse events or SAEs, no withdrawals due to adverse events and no headaches were reported in this trial. All adverse events were mild or moderate.

- 255. The statements referenced above in ¶254 were materially false and misleading when made because Defendant Salzmann made positive statements about IMVT-1401 but failed to disclose elevated cholesterol was a potential risk. Additionally, the clinical trial did not assess cholesterol so statements such as "designed to examine the initial safety" were misleading because Immunovant failed to test safety with respect to cholesterol levels.
- 256. During the 3/30/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

I think on the safety side, the FDA is going to look at the full range of a data package for any asset that's submitted. I think what we're really encouraged by in terms of our data to date is that all the adverse events that have been reported, both in our Phase I trial with healthy volunteers as well as in this trial, were just mild or moderate. We haven't had any SAEs....

- 257. The statements referenced above in ¶256 were materially false and misleading when made because Defendant Salzmann knew, or recklessly disregarded, that elevated cholesterol was a potential risk of IMVT-1401. Additionally, the statements "all the adverse events that have been reported, both in our Phase I trial with healthy volunteers as well as in this trial, were just mild or moderate, and "[w]e haven't had any SAEs" were materially false and misleading because Defendant Salzmann knew, or recklessly disregarded, that Immunovant was not testing for the potential risk of elevated cholesterol, so the clinical trial results were incomplete.
- 258. On or about April 10, 2020, the Company filed its Form S-1 Registration Statement with the SEC and Prospectus (the "4/10/20 Registration Statement"). The 4/10/20 Registration Statement was filed with respect to the sale of 11,389,969 shares of Immunovant common stock that may be sold by several selling stockholders from time to time. More than 4 million shares were registered with respect to shares beneficially owned by entities affiliated with Defendant Wong. The 4/10/20 Registration Statement contained the following table listing the selling shareholders:

Please see the section titled "Plan of Distribution" for further information regarding the stockholders' method of distributing these shares.

	Sha	Shares of Common Stock		
	Number		Number	
	Beneficially	Number	Beneficially	Percent
	Owned	Registered	Owned	Owned
	Prior to	for Sale	After	After
Name	Offering(1)	Hereby(2)	Offering	Offering
RTW Master Fund, Ltd.(3)	3,235,952	3,235,952		_
RTW Innovation Master Fund, Ltd.(3)	1,037,580	1,037,580	_	_
RTW Venture Fund Limited(3)	152,574	152,574	_	_
HanAll BioPharma Co., Ltd.(4)	636,805	636,805	_	_
Biotechnology Value Fund, L.P.	493,952	493,952	_	_
Biotechnology Value Fund II, L.P.	401,724	401,724	_	_
Biotechnology Value Trading Fund OS, L.P.	71,925	71,925	_	_
MSI BVF SPV L.L.C.	32,395	32,395	_	_
Health Sciences Holdings, LLC (Sponsor)(5)(6)	2,875,000	2,875,000	_	

259. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

ASCEND MG Trial

In August 2019, we initiated dosing in a randomized, blinded, placebo-controlled Phase 2a clinical trial of IMVT-1401 for the treatment of MG. *The ASCEND MG trial assesses safety and efficacy of IMVT-1401* in an anticipated 21 patients with MG symptoms, as defined by MGFA Class II through IVa, and QMG scores greater than or equal to 12 . . . *The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401* and identification of optimal dosing for Phase 3 administration through measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG . . . We anticipate reporting top-line results from this trial in the third quarter of calendar year 2020.

* * *

ASCEND GO-1 Trial

In May 2019, we initiated dosing in our ASCEND GO-1 trial, an open label single-arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with TED. We announced initial results from this trial in March 2020.... The primary endpoints of this trial are safety and tolerability of IMVT-1401 over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses ... The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. All adverse events were mild or moderate and there were no headaches reported.

* * *

ASCEND GO-2 Trial

In October 2019, we initiated dosing in our ASCEND GO-2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 patients with moderate-to-severe active TED with confirmed autoantibodies to TSHR. The ASCEND GO-2 trial explores the potential of IMVT-1401 to improve proptosis, and *assesses the*

safety and tolerability of IMVT-1401 in this population... The primary endpoints of this trial are the proptosis responder rate... and safety and tolerability... We currently anticipate reporting top-line results from this trial in the first half of calendar year 2021.

- 260. The statements referenced above in ¶259 were materially false and misleading when made because Defendants made positive statements about the IMVT-1401 clinical trial program and made it appear as if things were progressing smoothly but failed to disclose that elevated cholesterol was a key potential risk of IMVT-1401. The statement "[t]he ASCEND MG trial assesses safety and efficacy of IMVT-1401" was misleading because Immunovant failed to test cholesterol levels. Defendants' statements concerning ongoing clinical trials were also materially false and misleading. Contrary to Defendants' statements that the "Primary Endpoints" of the IMVT-1401 ASCEND GO-1 clinical trial included "Safety & Tolerability," Defendants knew, or recklessly disregarded, that elevated cholesterol was a potential risk and that those clinical trials had not monitored or assessed cholesterol, and as a result, those clinical trials failed to comply with Good Clinical Practices or procedures.
- 261. Additionally, the statements referenced above in ¶259 that "[t]he safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401" and "[a]ll AEs were mild or moderate" were misleading because Immunovant failed to test for the anticipated risk of elevated cholesterol levels and Immunovant, therefore, could not have been aware of "all AEs" that should have been tested under Clinical Good Practices. Furthermore, the statement that clinical trial results were consistent with prior tests as confirming the soundness of IMVT-1401 was materially false and misleading because the ASCEND GO-2 Phase 2b trial was assessing cholesterol while the other clinical trials did not.
 - 262. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

On March 30, 2020, we announced initial results from the ASCEND GO-1 trial. Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, four of seven patients (57%) improved by 2 points on the Clinical Activity Score (CAS).

- 263. The statements referenced above in ¶262 were materially false and misleading when made because Defendants highlighted the positive results of the clinical trial but failed to disclose elevated cholesterol was a potential risk which was not assessed.
 - 264. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

In several nonclinical studies and Phase 1 clinical trials in healthy volunteers, intravenous and subcutaneous delivery of IMVT-1401 demonstrated dose-dependent IgG antibody reductions and was observed to be well tolerated. In the highest dose cohort from the multiple-ascending dose portion of the Phase 1 clinical trial, four weekly subcutaneous administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, and the standard deviation of the reduction was 2%. In addition, no headaches, an adverse event seen with some FcRn agents, have been noted to date in any of the subjects receiving IMVT-1401 in the 680 mg multiple-dose cohort.

- 265. The statements referenced above in ¶264 were materially false and misleading when made because they highlighted the positive aspects of preclinical trials but failed to disclose the IMVT-1401 animal studies revealed elevations in cholesterol. The statement that "several nonclinical studies and Phase 1 clinical trials" were "observed to be well tolerated" was misleading because the animal studies revealed substantial increases in cholesterol, and it was unknown whether the "Phase 1 clinical trial" was "well tolerated" because Immunovant failed to test cholesterol levels.
- 266. The 4/10/20 Registration Statement stressed the safety of IMVT-1401, stating, in pertinent part, as follows:

Safety Data

In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo.... To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. There have been no treatment-related serious AEs reported.

- 267. The statements referenced above in ¶266 were materially false and misleading because Defendants failed to disclose elevations in cholesterol are a key potential risk of IMVT-1401 and those results did not include an assessment of cholesterol. The statement "observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was misleading because patients could have been suffering from elevated cholesterol. The statements about a lack of AEs were also misleading because it gave the impression that there were no elevated cholesterol levels even though Immunovant was not testing for cholesterol.
- 268. On April 14, 2020, the Company filed its 424B4 Prospectus (the "4/14/20 Prospectus") with the SEC in connection with a follow-on offering of 8,359,448 shares of Immunovant common stock at a price of \$14.50 per share. After the full exercise of the underwriters' allotment, \$139.4 million was raised from investors. The 4/14/20 Prospectus contained nearly identical representations about the Company, the testing of IMVT-1401, and the prospects and safety of IMVT-1401 as referenced in ¶259, 262, 264, and 266 above.
- 269. The statements referenced above in ¶268 were materially false and misleading when made for the reasons set forth in ¶¶260, 261, 263, 265, and 267.
- 270. On June 29, 2020, the Company announced its financial and operational results for the fourth quarter 2020, for the period ended March 31, 2020 ("4Q20"), and for the full year 2020 for the year ended March 31, 2020 ("FY20") in a press release (the "6/29/20 Press Release"), which

it filed with the SEC on Form 8-K. The 6/29/20 Press Release stated, in pertinent part, as follows:

In March, Immunovant announced positive clinical results from ASCEND GO-1, a Phase 2a trial of IMVT-1401 in Thyroid Eye Disease (TED), which reaffirmed IMVT-1401's prior safety and pharmacodynamic findings and demonstrated encouraging potential efficacy for patients with TED. Complementing these findings, two recent successful studies for other drug candidates with the same mechanism of action provided strong clinical validation in MG and demonstrated a within-study relationship between the degree of IgG lowering and the magnitude of clinical benefit in MG. With proof-of-biology now established for anti-FcRn agents in MG, Immunovant has chosen to accelerate Phase 3 development of IMVT-1401 in MG.

- 271. The statements referenced above in ¶270 were materially false and misleading when made because they highlight positive facts about IMVT-1401 but fail to disclose that a key potential risk of IMVT-1401 was elevated cholesterol and that the ASCEND GO-1 trial did not assess cholesterol. Additionally, "proof-of-biology" was materially false and misleading when made because the referenced clinical trials did not test for a potential risk of elevations in cholesterol and therefore Defendants lacked a reasonable basis to make that statement.
- 272. On June 29, 2020, Immunovant filed its annual report on Form 10-K with the SEC for FY20 (the "2020 Form 10-K"), which was signed by Defendants Salzmann, Torti, Fromkin, Hughes, Migausky, Pande, and Venker. The 2020 Form 10-K contained nearly identical representations about Immunovant, the testing of IMVT-1401, and the potential and safety of IMVT-1401, as contained in the 4/14/20 Prospectus and 4/10/20 Registration Statement, as referenced above in \$\Psi_259, 262, 264, 266, and 268.
- 273. The statements referenced above in ¶272 were materially false and misleading when made for the reasons set forth in ¶¶260, 261, 263, 265, 267, and 269.
- 274. For example, the 2020 Form 10-K discussed the safety of IMVT-1401, stating, in pertinent part, as follows:

Safety Data

In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 treatment-emergent AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours. . . . To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. There have been no treatment-related serious AEs reported.

- 275. The statements referenced above in ¶274 were materially false and misleading because Defendants failed to disclose that elevations in cholesterol are a key potential risk of IMVT-1401 and those results did not include an assessment of cholesterol. The statement "observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was misleading because patients could have been suffering from elevations in cholesterol. The statements about a lack of AEs were also misleading because it gave the impression that the IMVT-1401 clinical trials had assessed all key potential risks when that was not true.
- 276. On August 25, 2020, the Company announced results from the multi-center, placebo-controlled Phase 2a trial of IMVT-1401 in a press release (the "8/25/20 Press Release"), which it filed with the SEC on Form 8-K. The 8/25/20 Press Release stated, in pertinent part, as follows:

Consistent with previously reported Phase 1 results, *IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs)*, no withdrawals due to adverse events (AEs), and no imbalance in headaches. Mean reductions in total serum IgG from baseline for the 340 mg and 680 mg cohorts were 59% and 76%, respectively. "We are absolutely thrilled with the results of this trial," said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. "The clinical benefits we observed in this trial provide strong support that *IMVT-1401* might ultimately become a best-in-class anti-FcRn agent for MG patients.

277. The statements referenced above in ¶276 were materially false and misleading when made because Defendants failed to disclose elevations in cholesterol are a key potential risk of IMVT-1401 and those results did not include an assessment of cholesterol. The statement "IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs), no

withdrawals due to adverse events (AEs)" was materially false and misleading when made because Defendants lacked a reasonable basis for this statement because Immunovant failed to test for the potential risk of elevated cholesterol levels. Additionally, Defendant Salzmann lacked a reasonable basis to state that the clinical benefits provide strong support for IMVT-1401 to become "a best-in-class" drug because he knew, or recklessly disregarded, that the clinical trial had not assessed cholesterol risks and those would need to be assessed before IMVT-1401 could become "best-in-class."

278. On August 25, 2020, the Company held a conference call for analysts and investors (the "8/25/20 Conf Call"). During the 8/25/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

In line with our prior results, *IMVT-1401 was observed to be generally well tolerated with no grade 3 treatment-emergent adverse* events, no withdrawals due to adverse events and no imbalances in specific AEs.

* * *

On the safety and tolerability side, our results were consistent with prior Phase I and Phase II results for IMVT-1401. Namely no severe adverse events, no withdrawals due to adverse events and a rate of mild to moderate adverse events that was well balanced with placebo.

279. The statements referenced above in ¶278 were materially false and misleading when made because Defendant Salzmann failed to disclose elevations in cholesterol are a key potential risk of IMVT-1401 and those results did not include an assessment of cholesterol. The statement "observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was misleading because patients could have been suffering from elevations in cholesterol. The statements about the lack of AEs were also misleading because they gave the impression that the IMVT-1401 clinical trials had assessed all key potential risks when that was not true.

- 280. On or about September 1, 2020, Immunovant filed the September 2020 Offering Documents in connection with the September 2020 Offering. The representations in the September 2020 Offering Documents discussed Immunovant, the trials for IMVT-1401, and the safety of IMVT-1401 as referenced in ¶¶133, 134, 136, 137, 139, 141, 144, 146, 149, and 151 above. The September 2020 Offering Documents were materially false and misleading when made for the reasons set forth in ¶¶135, 136, 138, 140, 142, 143, 145, 147, 148, and 151.
- 281. On November 12, 2020, the Company participated in the Credit Suisse Healthcare Conference (the "11/12/20 Conf Call"). During the 11/12/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

And what did we see going back here to the summary of our Phase IIa open-label proof-of-concept trial? So first of all, we saw IgG reduction, which was as expected. This was primarily a 340-milligram regimen for 6 weeks. So the 65% reduction in IgG was consistent with what we had modeled this regimen would produce....

On the safety side, importantly, there were no serious adverse events. We actually saw no headaches in this trial either....

Finally, we have an ongoing study in thyroid eye disease that's much bigger than the proof of concept, and this is our *ASCEND GO-2 trial*. It's a pivotal design IIb trial, testing 3 different dosage arms with an emphasis on the 2 higher doses and comparing all those to placebo.

* * *

And then from a safety and tolerability standpoint, similar to our thyroid eye disease trial, a nice profile. Again, early days, but we're looking good from a safety and tolerability standpoint.

282. The statements referenced above in ¶281 were materially false and misleading when made because Defendant Salzmann made positive statements about the IMVT-1401 clinical trial program and made it appear as if things were progressing smoothly but failed to disclose that elevated cholesterol was a key potential risk of IMVT-1401. Defendant Salzmann's statement, "[o]n the safety side, importantly, there were no serious adverse events" was materially misleading

because elevations in cholesterol were a key potential risk so it was likely there were elevated cholesterol levels. Additionally, Defendant Salzmann lacked a reasonable basis to state there were no adverse events because he knew, or recklessly disregarded, that elevated cholesterol was a potential risk and that Immunovant had not assessed that risk. A reasonable investor would have expected Defendant Salzmann's statement to have incorporated an assessment of all key potential risks. Finally, Defendant Salzmann's statement about the ASCEND GO-2 Phase 2b trial was misleading because he discussed the positive aspects of that trial but failed to disclose that there was a risk that trial would be disrupted because it was assessing cholesterol, unlike the other clinical trials.

283. On January 12, 2021, Immunovant issued a press release titled "Immunovant Appoints Rita Jain Chief Medical Officer and Provides Corporate Update" (the "1/12/21 Press Release"), which it filed with the SEC on Form 8-K. The 1/12/21 Press Release quoted Defendant Salzmann who stated, in pertinent part, as follows:

We're extremely excited about the potential for IMVT-1401 in multiple therapeutic areas and have made good progress toward the initiation of our Phase 3 trial of IMVT-1401 in Myasthenia Gravis (MG), which remains on track for the first half of 2021[.] I'm also pleased with the team's progress developing INDs for new indications. We remain on track to announce three new indications by August of 2021[.]

284. The statements referenced above in ¶283 were materially false and misleading when made because Defendant Salzmann made positive statements about the IMVT-1401 clinical trial program and made it appear as if things were progressing smoothly but failed to disclose that elevated cholesterol was a key potential risk of IMVT-1401. Contrary to Defendant Salzmann's statement that the "Phase 3 trial of IMVT-1401 in Myasthenia Gravis (MG)" remains on track and that IMVT-1401 has "made good progress," Defendant Salzmann knew, or recklessly disregarded, that there was a substantial risk the IMVT-1401 clinical trial program would be disrupted. Indeed,

according to FE, by this time the Company had already begun its internal investigation into the elevations in cholesterol in the ASCEND GO-2 Phase 2b trial and it was likely other clinical trials would be disrupted as well.

Additional Misstatements and Omissions Regarding the Impact of Albumin Reductions and the Existence of Studies Indicating Albumin Reductions Elevate Cholesterol

285. During the 10/11/19 Merger Call, Defendants Salzmann and Wong responded to a question about albumin reductions in which Defendant Salzmann stated, in pertinent part, as follows: "In terms of albumin reductions, we did see *dose dependent reversible and asymptomatic albumin reductions* in the Phase 1 trial." And Defendant Wong stated, in pertinent part, as follows:

I would just add that there are – there's – the kind of "perfect knock out model" and that there are patients borne with close to 0% albumin and *those people in the literature are generally asymptomatic* with the exception of maybe a little bit of occasional edema, but they're basically healthy people.

- 286. The statements above in ¶285 were materially false and misleading because Defendants Salzmann and Wong minimized the negative impact of serum albumin reductions. The statements about a "perfect knock out model" and "asymptomatic" people born with "close to 0% albumin" were materially misleading because Defendant Wong was minimizing the relationship between decreases in serum albumin and increases in cholesterol.
- 287. On November 27, 2019, HSAC filed a Schedule 14A Proxy Statement (the "11/27/19 Proxy") with the SEC which stated, in pertinent part, as follows:

Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts. In the 680 mg multiple-ascending dose cohort, most subjects reached nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). These reductions were not associated with any AEs or clinical symptoms, and did not lead to any study discontinuations. The clinical relevance of isolated, mild hypoalbuminemia is unknown, however, a hereditary syndrome associated with deficient albumin production has been described (Congenital Analbumenia). In this syndrome, despite extremely low or

absent levels of albumin, those affected have only mild symptoms, including fatigue, low blood pressure and edema. It is believed that compensatory mechanisms through the production of other proteins may allow for relatively normal physiologic function in this population.

- 288. The statements referenced above in ¶287 were materially false and misleading when made because they minimized the negative impact of albumin reductions. The statements referenced above that "albumin reductions" were not "associated with any AEs or clinical symptoms and did not lead to any study discontinuations" were materially false and misleading because the albumin reductions were reported in scientific studies to be associated with the adverse events (AEs) of substantially increased cholesterol levels and Defendants lacked a reasonable basis to state there were no AEs because cholesterol was not assessed. Contrary to the statement "clinical relevance of isolated, mild hypoaluminemia is unknown," Defendants knew, or recklessly disregarded, medical and scientific studies and reports which discussed that hypoalbuminemia has emerged as a potentially powerful prognostic marker in coronary artery disease and elevates cholesterol. The reference to "mild" hypoalbuminemia was misleading because the albumin reductions observed in the IMVT-1401 trial were more substantial than "mild." Additionally, by stating that there were no "AE's" or "clinical symptoms" or "study discontinuations," the statements created the misleading impression that all potential risks were assessed even though the potential risk of elevated cholesterol levels were not measured.
- 289. The 11/27/19 Proxy, 1/17/20 Registration Statement, 4/10/20 Registration Statement, and the 2020 Form 10-K contained nearly identical language to that referenced in ¶240, 248, 250, 259, 262, 264, 266, 268, 272, 274, and 287 above and were materially false and misleading for the reasons set forth in ¶241, 249, 251, 260, 261, 263, 265, 267, 269, 273, 275, and 288 above.
- 290. On February 25, 2020, the Company presented at the 9th Annual SVB Leerink Global Healthcare Conference (the "SVB Conference"). Defendant Salzmann was quoted at the SVB

Conference and stated, in pertinent part, as follows:

So hypoalbuminemia, if you look at up, is the result of some very serious diseases. So normally if someone who has hypoalbuminemia, your differential diagnosis of physician might be severe liver disease, severe kidney disease, nephrotic syndrome, globally severe malnutrition but generally, hypoalbuminemia is part of the cause – I'm sorry, as a result of the condition, not a cause of a problem. In this case, we know what's causing the low albumin, which is a direct hindrance at the binding site. So the Fc receptor also recycles albumin and different assets have more or less interruption of that albumin binding site.

We have a little bit, and we did see a 20% to 30% reduction in albumin that leveled off, depending on the dose, 20% In the 340 arm, 30% in the 680 arm. That's not something that was associated with any adverse events or edema in the Phase 1 trial. And it's pretty hard to find any published literature or expert opinion on what the sequelae of a albumin – of a mild albumin reduction would be. So, we're not seeing any issues to date.

For albumin, we observed an average reduction of 24%. *Albumin changes were asymptomatic* in this trial as they were in Phase 1.

291. The statements referenced above in ¶290 were materially false and misleading when made because Defendant Salzmann knew, or recklessly disregarded, albumin reductions were reported in medical journals to elevate cholesterol levels and Defendant Salzmann minimized the impact of the albumin reductions. The statement that the "20% to 30% reduction in albumin" was not "associated with any adverse events or edema in the Phase 1 trial" was materially false and misleading because Defendant Salzmann knew, or recklessly disregarded, the reduction in albumin was associated with the potential risk of increased cholesterol. Since Immunovant failed to test for cholesterol, Defendant Salzmann did not have a reasonable basis for his statement. Finally, contrary to Defendant Salzmann's statement that "[a]lbumin changes were asymptomatic," the IMVT-1401 clinical trial did not monitor cholesterol so he was not in position to know whether the changes were asymptomatic and it was likely the albumin reductions elevated cholesterol in patients.

292. During the 8/25/20 Conf Call, Defendant Salzmann stated, in pertinent part, as

follows:

Reductions in albumin were also consistent with prior studies, with a 16% reduction observed in the 340-milligram arm and a 26% reduction observed in the 680-milligram arm. *All albumin reductions were asymptomatic*.

293. The statements referenced above in ¶292 were materially false and misleading when made because Defendant Salzmann knew, or recklessly disregarded, albumin reductions were reported in medical journals to elevate cholesterol levels and Defendant Salzmann minimized the impact of the albumin reductions. Contrary to Defendant Salzmann's statement that "[a]lbumin changes were asymptomatic," the IMVT-1401 clinical trial did not monitor cholesterol so he was not in position to know whether the changes were asymptomatic and it was likely the albumin reductions elevated cholesterol levels in patients.

Additional Misstatements and Omissions Regarding IMVT's Animal Studies

294. The 1/17/20 Registration Statement and 4/10/20 Registration Statement contained nearly identical language discussing the IMVT-1401 animal studies, stating in pertinent part, as follows:

Cynomolgus monkeys were selected as the primary species for preclinical testing, given the high degree of sequence homology to human FcRn and IMVT-1401's strong binding affinity for monkey FcRn. Our partner, HanAll, completed five preclinical studies of IMVT-1401 (referred as HL161BKN for the purposes of these studies) in cynomolgus monkeys. We are conducting two additional studies in cynomolgus monkeys.

295. The statements referenced above in ¶294 were materially false and misleading when made because they discussed the positive aspects of the animal studies but failed to disclose the negative fact that the IMVT-1401 animal studies revealed substantial elevations in cholesterol.

Immunovant's Class Period SEC Filings Omitted Known Trends, Events and Uncertainties that Were Impacting, and Would Impact, the Company's Financial Results

296. Pursuant to Item 7 of Form 10-K and Item 2 of Form 10-Q, Immunovant's Class Period SEC filings were required to furnish the information required under Item 303 of Regulation S-K [17 C.F.R. §229.303], including any known trends, events or uncertainties that have caused or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results.

297. The known trends, events, or uncertainties referenced in ¶153 above were having, and were reasonably likely to have, an impact on the Company's continuing operations and, therefore, were required to be disclosed by Defendants pursuant to Item 303 in the 1/17/20 Registration Statement, the 4/10/20 Registration Statement, the 4/14/20 Prospectus, the 2020 Form 10-K, and the September 2020 Offering Documents, but were not.

Immunovant's Class Period SEC Filings Omitted to Include Significant Risk Factors Required to Be Disclosed Therein

- 298. Pursuant to Item 1A of Form 10-K, Immunovant's 2020 Form 10-K was required to furnish the information pursuant to Item 105 of Regulation S-K [17 C.F.R. §229.105], including, among other things, "a discussion of the material factors that make an investment in the registrant or offering speculative or risky." Pursuant to Item 1A of Form 10-Q, Immunovant's Class Period Forms 10-Q were required to "[s]et forth any material changes from risk factors as previously disclosed" in Immunovant's 2020 Form 10-K pursuant to Item 105 of Regulation S-K [17 C.F.R. §229.105]. Defendants failed to comply with Item 105 by failing to disclose risk factors or material changes in risk factors in these SEC filings.
- 299. Specifically, Defendants failed to disclose the risk factors set forth in ¶157 above in Immunovant's 1/17/20 Registration Statement, the 4/10/20 Registration Statement, the 4/14/20 Prospectus, the 2020 Form 10-K, and the September 2020 Offering Documents as required under

Item 105.

300. Additionally, any purported risk warnings or cautionary language provided by Defendants during the Class Period, including the language referenced in ¶159, 161, and 163 above, did not adequately warn investors about the materially false and misleading statements alleged herein. These risk warnings: (i) were false or misleading as a matter of current or historical fact; and/or (ii) were not meaningful because, among other things, they were vague, boilerplate and did not adequately warn of the true risks of investing in Immunovant.

ADDITIONAL SCIENTER ALLEGATIONS

- 301. As alleged herein, the Defendants acted with scienter in that Defendants knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company (or in their own name) were materially false and misleading; knew or recklessly disregarded, that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Immunovant and IMVT-1401, their control over, and/or receipt and/or modification of Immunovant's allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.
- 302. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Exchange Act Individual Defendants.
 - 303. Defendant Salzmann was a highly experienced and knowledgeable professional in the

biopharmaceutical industry and had extensive experience with clinical trials of drugs. Indeed, prior to his employment at the Company, he served as Global Brand Development Leader in Immunology at Eli Lilly, where he designed and executed a comprehensive indication development strategy and oversaw Phase 2 and 3 clinical trial execution (from November 2018 to June 2019). From March 2013 to October 2018, Defendant Salzmann was Head of U.S. Immunology at Eli Lilly, and Managing Director of Lilly Alps from January 2011 to April 2013. From January 2008 to December 2010, Defendant Salzmann was the Head of Marketing for Eli Lilly China. Defendant Salzmann also served during the Class Period as a member of the board of directors of Corbus Pharmaceuticals Holdings, Inc., a publicly traded biotechnology company.

- 304. Under Good Clinical Practices and FDA rules and regulations, Immunovant was obligated to search for and review relevant scientific studies and Defendant Salzmann, as the CEO of Immunovant, would have been made aware of potential risks. Defendant Salzmann would have been aware of the science and the scientific literature related to serum albumin, thyroid levels, and other issues that made elevated LDL and cholesterol levels a potential risk of IMVT-1401. Defendant Salzmann would also have been aware that according to Good Clinical Practices and standards, Immunovant should have designed each of its phase 1 and 2 trials to test for and report on all key potential risks, including cholesterol levels, due to the potential risk of elevated cholesterol based on the science, the scientific literature, and Immunovant's animal study results showing a substantial increase in cholesterol for animals which received IMVT-1401.
- 305. Defendants Salzmann, as CEO at Immunovant, at a minimum, should have been aware of key facts related to the testing and risks involved with IMVT-1401, including that the animal studies showed an increase in cholesterol, that an increase in cholesterol levels was an anticipated risk of IMVT-1401, and that the completed clinical trials of IMVT-1401 had not tested

for cholesterol and that the ASCEND GO-2 Phase 2b trial was the first time the Company tested for cholesterol in clinical trials.

- 306. Further, Defendant Salzmann, as the CEO of the Company and with his scientific background, would have been directly involved with the design, approval and/or review of the IMVT-1401 clinical trials as well as the preparation and/or review of all reports and studies that were provide to the FDA concerning IMVT-1401, including the animal studies showing an increase in cholesterol and information concerning the trial protocols, including the lack of cholesterol testing in early clinical trials, as well as the fact that the ASCEND GO-2 Phase 2b trial protocol included assessments of cholesterol.
- 307. Defendant Roivant knew or recklessly disregarded the fraud alleged herein. Defendant Roivant first acquired the license for IMVT-1401, then formed Legacy Immunovant, then sold it to HSAC in the Merger, and continued its control over Immunovant after the Merger. At all relevant times herein, Immunovant was a subsidiary of Roivant and was dependent upon Roivant for important business and drug development functions and services. Immunovant was also required to provide information about IMVT-1401 and other business information to Roivant pursuant to various agreement entered into between the entities.
- 308. Defendant Wong knew or recklessly disregarded the fraud alleged herein. Defendant Wong would have initially learned the details about IMVT-1401 in connection with his investment in Legacy Immunovant. During the 10/11/19 Merger Call, Defendant Wong admitted, "we've been tracking the development of IMVT-1401 for several years now as part of our competitive analysis of the FcRn drug class." Two days after the IPO of his SPAC, HSAC, Defendant Wong contacted Legacy Immunovant about a potential Merger. Wong was the CEO and primary investor in HSAC and was intimately involved with the process which resulted in HSAC's acquisition of Legacy

Immunovant. As alleged above, HSAC and Defendant Wong engaged in talks for approximately one year about HSAC acquiring Legacy Immunovant and Wong, through HSAC, engaged in formal due diligence from at least May 11, 2019, to September 29, 2019. Through this due diligence, Defendant Wong would have known, or was reckless in not knowing, that increased cholesterol levels were a key potential risk of IMVT-1401, that the clinical trials for IMVT-1401 prior to the ASCEND GO-2 Phase 2b trial failed to test for cholesterol, and that the animal studies for IMVT-1401 revealed substantially increased cholesterol levels in test animals.

- 309. Defendant Wong would have had access to and would have reviewed the protocols and results from the pre-clinical and clinical studies, including the ASCEND GO-2 Phase 2b trial which monitored cholesterol while the others did not. Additionally, Defendant Wong remained a beneficial owner of a large amount of Immunovant securities, controlled one director, and had the right to obtain additional shares of Immunovant after the Merger. Furthermore, Defendant Wong knew about or recklessly disregarded the literature and studies indicating albumin reductions elevate cholesterol. Defendant Wong acknowledged during the HSAC and Legacy Immunovant Merger Call, on October 11, 2019, that he reviewed scientific literature about potential side effects of albumin reductions in support of his misleading statement that "people in the literature are generally asymptomatic." Accordingly, a reasonable inference is that Defendant Wong also knew about, or recklessly disregarded, the studies stating albumin reductions elevate cholesterol.
- 310. Furthermore, the fraud alleged herein related to testing and development of IMVT-1401, which was the core and sole business of Immunovant, so knowledge of the fraud may be imputed to Defendants. Immunovant was a small company with only approximately 19 employees during 2019 and 42 employees during 2020. Since Immunovant had no other drugs or products other than IMVT-1401, and since IMVT-1401 was in ongoing clinical trials during the

Class Period, knowledge of the fraud may be imputed to Defendants.

- 311. Likewise, the Exchange Act Individual Defendants, by virtue of their high-level positions with the Company or HSAC, directly participated in the management of the Company or HSAC, were directly involved in the day-to-day operations of the Company or HSAC at the highest levels and were privy to confidential proprietary information concerning the Company or HSAC and IMVT-1401, as alleged herein. The Exchange Act Individual Defendants had the ultimate authority over and were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements regarding the Company were being issued, and approved or ratified these statements, in violation of the federal securities laws.
- 312. In addition, Defendants also possessed knowledge of facts or had access to information contradicting their public statements. Defendants failed to review or check information that they had a duty to monitor or ignored obvious signs of fraud. Defendants knew, or had access to, among other things, the IMVT-1401 animal studies, scientific information showing that elevated cholesterol levels were an anticipated risk of IMVT-1401, and details about the clinical trial protocols, including that Immunovant had not tested for cholesterol during the Phase 1 trials or any Phase 2 trials completed prior to the ASCEND GO-2 Phase 2b trial. Accordingly, Defendants were in possession of, or had access to, facts indicating that Defendants' statements about the safety of IMVT-1401 were materially false and misleading, and that there was a substantial risk that the IMVT-1401 clinical trial program could be delayed or disrupted due to issues with cholesterol.
- 313. Additionally, Defendants possessed substantial motives for misrepresenting the safety of IMVT-1401 throughout the Class Period.
 - 314. Defendant Wong had a substantial financial motive for engaging in the fraud alleged

herein. Defendant Wong, through entities under his control, founded the blank-check company HSAC. He, therefore, had a financial motive to ensure that HSAC acquired a company within two years so he would not need to return the capital raised from investors. Defendant Wong also had a financial motive for HSAC to acquire Legacy Immunovant because Defendant Wong had owned shares in Legacy Immunovant since before HSAC's IPO. Since Defendant Wong contacted Legacy Immunovant about the Merger two days after HSAC's IPO, an inference can be drawn that Wong sought to acquire Legacy Immunovant before the IPO.

- 315. Similarly, Defendant Roivant, as the controlling shareholder of Legacy Immunovant, was financially motivated to engage in the fraud alleged herein to monetize its investment in IMVT-1401 and Immunovant by selling Legacy Immunovant to HSAC and then profiting from its ownership of Immunovant.
- 316. Furthermore, the structure of the SEA in connection with HSAC's acquisition of Legacy Immunovant provided strong financial motivation for Defendants Roivant, Immunovant, and Wong to engage in the fraud alleged herein. Under the terms of the SEA, the "Sellers" of Legacy Immunovant, including Defendants Roivant and Wong, were entitled to receive up to 20 million "earnout shares" of Immunovant common stock if the stock price exceeded pre-defined targets. The earnout shares provision states, in pertinent part, as follows:

Earnout Shares

The Sellers are entitled to receive up to an additional 20,000,000 shares of the Company's common stock (the "Earnout Shares") if the volume-weighted average price of the Company's shares equals or exceeds the following prices for any 20 trading days within any 30 trading-day period (the "Trading Period") following December 18, 2019, the date of the closing of the Business Combination:

- (i) during any Trading Period prior to March 31, 2023, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least \$17.50 per share; and
 - (ii) during any Trading Period prior to March 31, 2025, 10,000,000 Earnout

Shares upon the achievement of a volume-weighted average price of at least \$31.50 per share (each of (i) and (ii) are a "Milestone").

- 317. At the time the merger was approved, Immunovant common stock traded at \$11.49 per share, it exceeded \$17.50 per share on May 12, 2020, and exceeded \$31.50 on September 17, 2020. Therefore, those that were entitled to the earnout shares were in position to financially benefit from the artificial inflation of the price of Immunovant common stock. The artificial inflation in the price of Immunovant common stock enabled Defendants Roivant and Wong to qualify for and receive the earnout shares during the Class Period.
- 318. Defendants Roivant and Wong were motivated to artificially inflate the price of Immunovant shares and delay disclosing to investors that elevated cholesterol levels were a potential risk of IMVT-1401 until after they received their lucrative earnout shares. The artificial inflation in the price of Immunovant shares enabled Roivant, Wong and others to earn the first tranche of 10 million earnout shares on May 12, 2020 when the price of Immunovant stock was at \$22.70 per share (valued at \$227 million) and earn the second tranche of 10 million earnout shares when the price of Immunovant was \$38.43 per share (\$384 million). Collectively, Defendants Roivant, Wong and other Legacy Immunovant shareholders received 20 million earnout shares valued at more than \$611 million on the dates they were earned.
- 319. Even if Defendant Roivant and Defendant Wong's affiliated entities sold zero shares, the fraud was still profitable. On February 2, 2021, after Immunovant announced the halting of the clinical trial at the end of the Class Period which caused a 42% decline in the price of Immunovant shares, the earnout shares were valued at more than \$500 million. Therefore, on the day that Plaintiff and the Class suffered losses because of Defendants' fraud, Roivant, Wong and others had a \$500 million profit. Moreover, Defendant Salzmann was not harmed by the decline in the Company's shares because as reflected in Immunovant's Form Def. 14A filed with the SEC, the

Company repriced his options in the Company so that those options would still be valuable even after the decline in Immunovant stock.

320. Additionally, the artificial inflation of the price of Immunovant common stock enabled Immunovant and various selling shareholders, including entities controlled and owned by Defendant Wong, to sell hundreds of millions of dollars of Immunovant common stock to investors through several public follow-on offerings and shelf registrations, including on or about April 10, 2020, April 14, 2020, and September 2, 2020. In fact, on or about January 15, 2021, approximately two weeks before Immunovant announced the halting of its IMVT-1401 trials on February 2, 2021, Immunovant filed a registration statement for a shelf offering for \$150 million worth of common stock and selling stockholders, including entities controlled by Defendant Wong, filed a prospectus for the sale of nearly one million shares of Immunovant common stock. The timing of these stock registrations as so close to the announcement of the halting of the Immunovant's phase 2 studies supports scienter.

321. Below is a chart which summarizes some of Defendants' financial motivations to engage in the fraud alleged herein:

Date	Deal / Event	Who Benefitted and By How Much	IMVT (HSAC) Stock Price
05/10/2019	HSAC IPO: Raised \$115 million from public investors	 \$115 million raised from public investors Roderick Wong (CEO of HSAC) Funds from IPO must be returned if HSAC does not make acquisition within 24 months 	\$10.00 per unit
09/29/2019	HSAC acquisition of Legacy Immunovant Announced	 Roivant controlling Legacy Immunovant shareholder Roderick Wong beneficially owns 2,604,166 of Legacy Immunovant shares or 3% of Legacy Immunovant 	\$10.02 per share

Date	Deal / Event	Who Benefitted and By How Much	IMVT (HSAC) Stock Price
12/16/2019	HSAC acquisition of Legacy Immunovant Approved	 Transaction valued at \$421,802,770 Selling shareholders include Roivant; Roderick Wong entities RTW Master Fund and RTW Innovation Fund; and HanAll Biopharma Co., Ltd. Selling shareholders entitled to up to 10 million shares if IMVT exceeds \$17.50 Selling shareholders entitled to up to 10 million shares if IMVT exceeds \$31.50 	\$11.49 per share
04/09/2020	Registered shelf public offering by selling shareholders listed in the next column	 RTW Master Fund, Ltd.: owned 3,235,952 shares and registered 100% RTW Innovation Master Fund, Ltd.: owned 1,037,580 shares and registered 100% RTW Venture Fund Limited: owned 152,574 and registered 100% Health Sciences Holdings, LLC (Sponsor): owned 2,875,000 and registered 100% HanAll BioPharma Co., Ltd. 	\$15.54 per share
04/14/2020	Immunovant follow-on offering	Immunovant raised \$139.4 million from public investors	\$14.50 per share
09/02/2020- 09/04/2020	Immunovant follow-on offering	Immunovant raised \$200 million from investors	\$33.00 per share
01/15/2021	Registered shelf public offering of nearly 1 million shares of Immunovant common stock by selling shareholders listed in the next column	 RTW Master Fund, Ltd.: registered 662,912 for sale RTW Innovation Master Fund, Ltd.: registered 174,241 for sale HanAll Biopharma Co., Ltd. The shares registered for sale consist of additional shares issued to each stockholder in September 2020 upon the achievement of the second earnout milestone 	\$44.15 per share
01/15/2021	Immunovant filed registration statement for shelf offering of common stock	Registered for sale of up to \$150 million in Immunovant common stock to public investors	\$44.15 per share

322. Taken collectively, the facts alleged above demonstrate a strong inference that Defendants acted with scienter.

LOSS CAUSATION/ECONOMIC LOSS

- 323. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct which artificially inflated the prices of Immunovant common stock and operated as a fraud or deceit on Class Period purchasers of Immunovant securities. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of Immunovant common stock fell precipitously as the prior artificial inflation came out. As a result of their purchases of Immunovant common stock during the Class Period, Plaintiff and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.
- 324. Defendants' false and misleading statements, which as alleged above were made without any reasonable basis, had the intended effect and caused Immunovant common stock to trade at artificially inflated levels throughout the Class Period.
- 325. On February 2, 2021, Immunovant announced the voluntary pause in clinical dosing of IMVT-1401 as a result of patients experiencing an increase in LDL and cholesterol levels, as set forth in ¶¶8, 99-100, 167 above. In response to the Company's announcement on February 2, 2021, shares of the Company's stock fell \$18.22 per share, or 42.08%, from a close of \$43.30 per share before the announcement, to close at \$25.08 per share, on extremely heavy trading volume of 11.76 million shares.
- 326. Then, on June 1, 2021, the Company announced additional details about the connection between IMVT-1401 and cholesterol, including, among other things, that the observed increases in LDL and cholesterol appeared to be caused by a reduction in albumin levels and relate to all indications of IMVT-1401. In response to the Company's announcements on June 1, 2021, shares of the Company's stock fell from \$5.76 per share, or 38%, from a close of \$15.16 per share before the announcement, to close at \$9.40 per share, on extremely heavy trading volume of 16.92

million shares.

327. The declines in the price of Immunovant common stock after the disclosures came to light was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market and a materialization of the undisclosed risks alleged herein. The timing and magnitude of the price declines in Immunovant common stock negates any inference that the loss suffered by Plaintiff and the other Class members were caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Immunovant securities and the subsequent significant declines in the value of Immunovant securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed and there was a materialization of the undisclosed risks.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

- 328. At all relevant times, the market for Immunovant common stock was an efficient market for the following reasons, among others:
- (a) Immunovant common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) as a regulated issuer, Immunovant filed periodic public reports with the SEC and the NASDAQ;
- (c) Immunovant regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

- (d) Immunovant was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.
- 329. As a result of the foregoing, the market for Immunovant securities promptly digested current information regarding Immunovant from all publicly available sources and reflected such information in the prices of the securities. Under these circumstances, all purchasers of Immunovant securities during the Class Period suffered similar injury through their purchase(s) of Immunovant securities at artificially inflated prices and a presumption of reliance applies.

APPLICABILITY OF PRESUMPTION OF RELIANCE: AFFILIATED UTE DOCTRINE

- 330. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because Defendants' material omissions during the Class Period caused harm to Plaintiff and the Class. Because the Complaint alleges Defendants' failure to disclose material adverse information regarding Immunovant and the testing, safety and prospects of IMVT-1401 information that Defendants were obligated to disclose positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions.
- 331. Given the importance of the Class Period material omissions set forth above, that requirement is satisfied here, and, therefore, *Affiliated Ute* provides a separate, distinct basis for finding the applicability of a presumption of reliance.

NO SAFE HARBOR

332. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of the company making the statement who knew that those statements were false or misleading when made.

COUNT IV

Violations of Section 10(b) of the Exchange Act and Rules 10b-5(a), (b), and (c) Promulgated Thereunder Against Immunovant, Roivant and the Exchange Act Individual Defendants

- 333. Plaintiff repeats and realleges each and every allegation contained above in ¶1-194, 216-327 as if fully set forth herein.
- 334. This Count is asserted against Immunovant, Roivant and the Exchange Act Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- 335. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other

members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Immunovant securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Immunovant securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

- 336. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Immunovant securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Immunovant's finances and business prospects.
- 337. By virtue of their positions at Immunovant and/or HSAC, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each

Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

- 338. Defendant Wong participated in the business combination process including the conducting of a due diligence investigation into Immunovant. Defendant Wong was HSAC's CEO prior to its acquisition of Immunovant and is substantially intertwined in Immunovant's business, studies, and IMVT-1401 drug candidate through the RTW Entities. Defendant Wong, through the RTW Entities, owned approximately 3% of the shares of Legacy Immunovant. By virtue of his involvement with Immunovant, Defendant Wong had actual knowledge of the materially false and misleading statements and omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendant Wong acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants.
- 339. Immunovant began as a division of Roivant. Defendant Roivant was a controlling shareholder of Legacy Immunovant and Immunovant at all times relevant herein. Defendant Roivant was the majority selling shareholder in the sale of Legacy Immunovant to HSAC, and remained a controlling shareholder after the sale. Roivant was intimately involved with IMVT-1401, including the licensing of IMVT-1401 from HanAll, and, acted knowingly or with reckless disregard for the truth.
- 340. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Immunovant and/or HSAC, the Exchange Act Individual Defendants had knowledge of the details of Immunovant's internal affairs.

- 341. The Exchange Act Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Exchange Act Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Immunovant. As officers and/or directors of Immunovant and/or HSAC, the Exchange Act Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Immunovant's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Immunovant securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning IMVT-1401 and Immunovant which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Immunovant securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants and were damaged thereby.
- 342. During the Class Period, Immunovant securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Immunovant securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Immunovant securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Immunovant securities declined sharply upon public

disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

- 343. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 344. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT V

Violations of Section 20(a) of the Exchange Act Against the Exchange Act Individual Defendants and Roivant

- 345. Plaintiff repeats and realleges each and every allegation contained above in ¶1-194, 216-344 as if fully set forth herein.
- 346. Defendants Salzmann and Roivant were controlling persons of Immunovant and Defendant Wong was a controlling person of HSAC.
- 347. During the Class Period, the Individual Defendants participated in the operation and management of Immunovant or HSAC, and conducted and participated, directly and indirectly, in the conduct of Immunovant's or HSAC'a business affairs. Because of their senior positions, they knew the adverse non-public information about Immunovant's business and IMVT-1401.
- 348. As officers and/or directors of Immunovant or HSAC, the Exchange Act Individual Defendants had a duty to disseminate accurate and truthful information with respect to IMVT-1401 and Immunovant's business and prospects, and to correct promptly any public statements issued by Immunovant which had become materially false or misleading.
 - 349. Because of their positions of control and authority as senior officers at Immunovant

or HSAC, the Exchange Act Individual Defendants, were able to, and did, control the contents of the various reports, press releases and public filings which Immunovant or HSAC disseminated in the marketplace during the Class Period concerning Immunovant and IMVT-1401. Throughout the Class Period, the Exchange Act Individual Defendants exercised their power and authority to cause Immunovant to engage in the wrongful acts complained of herein. The Exchange Act Individual Defendants, therefore, were "controlling persons" of Immunovant within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Immunovant securities.

- 350. Each of the Exchange Act Individual Defendants, therefore, acted as a controlling person of Immunovant. By reason of their senior management positions and/or being directors of Immunovant or HSAC, each of the Exchange Act Individual Defendants had the power to direct the actions of, and exercised the same to cause, Immunovant to engage in the unlawful acts and conduct complained of herein. Each of the Exchange Act Individual Defendants exercised control over the general operations of Immunovant and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.
- 351. Furthermore, Defendant Roivant was a control person of Legacy Immunovant and Immunovant at all relevant times herein. Immunovant began as a division of Roivant and Roivant owned more than a majority of Immunovant stock during the Class Period and had, and exercised control over, Immunovant.
- 352. By reason of the above conduct, the Exchange Act Individual Defendants and Roivant are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Immunovant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Declaring this action to be a class action properly maintained pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure;
- B. Awarding Plaintiff and other members of the Class damages together with interest thereon;
 - C. With respect to Count II, ordering that the September 2020 Offering be rescinded;
- D. Awarding Plaintiff and other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees, accountants' fees and experts' fees and other costs and disbursements; and
- E. Awarding Plaintiff and other members of the Class such other and further relief as may be just and proper under the circumstances.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

DATED: March 17, 2023

ROBBINS GELLER RUDMAN & DOWD LLP SAMUEL H. RUDMAN EVAN J. KAUFMAN NATALIE C. BONO

/s/ Evan J. Kaufman
EVAN J. KAUFMAN

58 South Service Road, Suite 200 Melville, NY 11747 Telephone: 631/367-7100 631/367-1173 (fax) srudman@rgrdlaw.com ekaufman@rgrdlaw.com nbono@rgrdlaw.com

Lead Counsel for Lead Plaintiff